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The Journal of the Connecticut State Medical Society

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Multiple Systemic Lipomatosis

ROBERT J. JOHNSON, M.D., WILLIAM R. PRESKENIS, M.D.,
LUIS F. DIEZ-MORALES, M.D. AND ANTHONY S. MORGAN, M.D.

A Case Report

ABSTRACT–A patient with multiple systemic lipomatosis is described. Patient presented with numerous subcutaneous masses on his torso and extremities and was found to have an increased pre-Beta lipoprotein which is consistent with Type 4 hyperlipoproteinemia. Patient underwent extensive surgical excisions of multiple lipomas and fibrolipomas. The pathogenesis of this disorder remains obscure and surgical excision of the aesthetic deformity remains the only albeit palliative treatment.

Introduction

Multiple systemic lipomatosis (MSL) known also as Madelung's Disease or the Launois and Bensaude Syndrome is an uncommon malformation of the tissue which can in some cases lead to gross distortions of the patient's physiogomy. The underlying metabolic derangement in this disease is as yet unknown. Patients with MSL either seek or are referred for surgery for correction of the aesthetic deformity. Here we present and discuss a case of this relatively rare disorder.

Case Report

The patient presented as a 32-year-old Hispanic male who complained of 15 years of progressive growth and spread of "lumps" on his trunk and extremities. He first recalled a growth beneath the skin on the extensor aspect of his right forearm at age 17. This initial growth continued to enlarge and subsequently developed additional masses beneath the skin on all four extremities as well as his trunk. The head, feet and hands were spared. The masses progressed to varying sizes and were continuous in some areas. They never receded in size during this 15-year period. Some were slightly tender at times but most were not. At no time had the masses disrupted the integrity of the skin overlying them. The degree of deformity due to the large number of subcutaneous masses, particularly on his extremities, cause significant emotional stress and prompted the patient to keep his limbs covered at all times in public.

His past medical history was unremarkable and he was taking no medications. He did not recall significant infections or industrial exposures. He recalled an uncle who had similar masses but of far fewer number and smaller in size. Neither his siblings nor his parents had any similar findings according to the patient.

Physical examination revealed a well nourished, well-developed Hispanic male with a pulse of 88, blood pressure of 130/86 and afebrile. He had multiple subcutaneous masses of varying sizes between 2 and 5 cm, some contiguous particularly on the forearms. The largest were on the forearms and on the lower back, where they were mildly tender with the skin under some tension. The masses were moderately firm and were fixed to underlying tissue. They were equally distributed between flexor and extensor surfaces of the extremities with sparing of hands and feet (Figure 1).

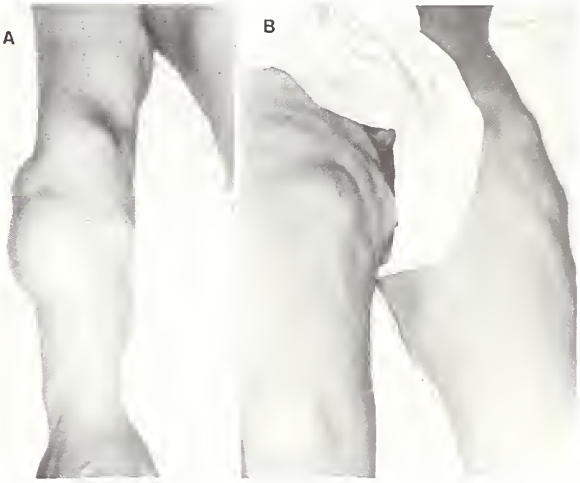

Figure 1
Patient's right arm and upper legs with multiple lipomatous masses.

The head and neck were normal. Cardiovascular, lung and abdominal examinations were unremarkable. There was no adenopathy. There were no neurological deficits.

ROBERT J. JOHNSON, M.D., Fellow, Department of Cardio-Thoracic Surgery, University of Utah Medical Center, Salt Lake City, UT. WILLIAM R. PRESKENIS, M.D., Resident, Department of Medicine, Saint Francis Hospital and Medical Center. LUIS F. DIEZ-MORALES, M.D., Director, Medical Outpatient Services, Saint Francis Hospital and Medical Center. ANTHONY S. MORGAN, M.D., Director, Trauma Services, Saint Francis Hospital and Medical Center, Hartford, CT.

Laboratory exams revealed normal electrolytes, CBC, and liver function studies. The erythrocyte sedimentation rate was 12 mm/hr. Triglycerides were marginally elevated at 252 mg/dl, high density lipoproteins elevated at 43.4 mg/dl (NL 39-96) and lipoprotein electrophoresis, showed an increased pre-Beta (VLDL) fraction, consistent with a Type IV hyperlipoproteinemia. Cholesterol was normal. Ultrasound of a large mass on the right forearm revealed the structure to be non-cystic and essentially solid. Tagged red blood cell study with Tc-99m pertechnetate failed to demonstrate any increased flow in either early static images or delayed blood pool images to the masses in both forearms. Patient underwent excision of a total of 204 lipomas under general anesthesia in two separate operating sessions (Figure 2). Microscopic examination revealed the tumors to be composed of mature adipose tissue, with occasional scattered foci of fibrosis and increased vascularity. There was no evidence of malignancy (Figure 3).

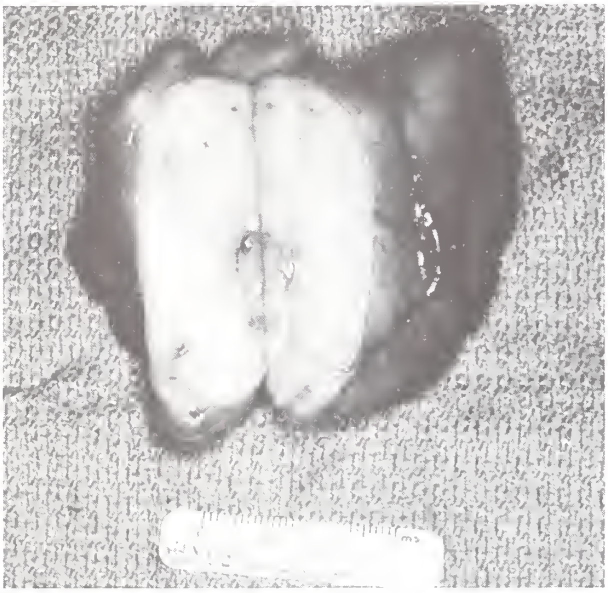

Figure 2
Cut gross appearance of one lipoma.

Discussion

Madelung first described the clinical syndrome of symmetrical lipomatosis when he reported 33 cases in 1846.[1] Launois and Bensaude reported 65 more cases in 1898.[2] Since then approximately 170 cases have been reported by Enzi in 1984.[3] While Madelung described the disorder as consisting of abnormal deposits of adipose/tissue in the upper torso, primarily in the cervical and supraclavicular regions of the neck, Enzi[3] further described the distributions of the lesions on the lower abdomen and thighs that occurred in approximately 40 to 50% of these patients. The patient that we report in addition had lipofibromas distributed symmetrically over the upper and lower arms and lower thighs. The fatty tumors were well circumscribed masses protruding from the body surface, which places them in the MSL of Type I class of patients. This patient, however, weighed 83 kilos and did not fit the general description provided by Enzi[3] of MSL Type I patients being underweight. This patient had no signs of mediastinal involvement and his chest x-ray was normal.

Figure 3
Microscopic section showing mature adipose tissue with scattered foci of fibrosis.

The patient first noticed his tumorous growths at age 17 and did not seek medical advice until age 32. He also reports a maternal uncle who has a history of what may be multiple lipomas. In previous series and case reports the appearance of lipomas has occurred most often during or after the third decade, whereas this patient's first eruptions occurred in the middle of his second decade. Familial lipomatosis is a rare hereditary disease which occurs as an autosomal dominant inheritance with variable penetration.[4, 5, 6] An autosomal dominant disorder consisting of macrocephaly, lipomas, hemangiomas, and a propensity for intracranial tumors was described by Bannayan in 1971.[7, 8]

This patient described a maternal uncle who had multiple skin growths, but this was not confirmed by direct observation. There were no other reported family members affected with the disease. Most reports have associated MSL with increased alcohol intake;[3] however, this patient denied alcohol abuse, which was confirmed by family members. The neurologic examination has been reported as showing peripheral motor and sensory neuropathies, including loss of vibratory sensation, hypoesthesias, muscular weakness, tremor flapping, and absent tendon reflexes.[3] Our patient, however, showed none of these.

It is possible that these findings could be secondary to the observed alcohol abuse seen in other reported patients. As such, electromyography was not performed. The patient also had no other associated diseases and his fasting glucose was normal. The only laboratory study of note was an elevated tryglyceride level. His lactoprotein electrophoresis showed an increase in the pre-beta lipoprotein and was thought to represent a Type IV hyperlipoproteinemia. Enzi[3] noted that there was a significant increase in high density lipoprotein fraction, even in those patients who had Type IV hyperlipoproteinemia. This hyperalphalipoproteinemia is unusual in those patients with Type IV or Type V hyperlipoproteinemia where the alpha fraction is usually diminished. Our patient did not correspond to this pattern. Increased levels of high density lipoprotein can be seen in chronic alcoholics as previously documented.[9-11] Pagnan[12] found in MSL patients no correlation between daily alcohol intake and HDL or HDL_2 levels. He concluded that the elevated alcohol intake levels in those patients could not fully explain the marked elevations in the high density lipoprotein level. Moreover, Enzi[11] found that those MSL patients with Type IV hyperlipoproteinemias had increased levels of high density lipoproteins and believed that this supported the diagnosis of a primary hyperalphalipoproteinemia in addition to the increased pre-beta hyperlipoproteinemias. Histopathology on the 204 removed tumors revealed mature adipose tissue with scattered foci of fibrosis and occasional increased vascularity. There was no evidence of malignancy. There has been only one case report of malignant degeneration in Madelung's disease.[13] This degeneration occurred spontaneously after the consistency and size of the tumor had changed. The only treatment for this problem at present is excision of the lipomas. This is done both for cosmesis and in those patients with mediastinal involvement for functional improvement. This does not guarantee the eradication of the disease, and it is not unusual for more tumors to appear over the succeeding years. However, excision of these tumors is accompanied by a marked increase in the patient's psychological well-being and social confidence. The multiple scars are evidently psychologically more acceptable than are the multiple tumor growths.

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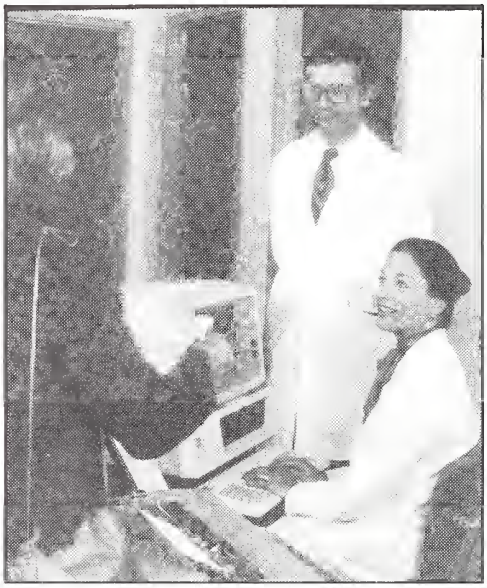

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Upper Airway Obstruction in Achalasia

ERIC TEN BROCK, M.D. AND DANIEL McNALLY, M.D.

ABSTRACT–Achalasia is an esophageal disorder with some well known pulmonary complications. One uncommon complication that is rarely described is upper airway obstruction due to megaesophagus. This can be life threatening and awareness of its occurrence is essential for prompt and effective therapy.

Introduction

Achalasia is an uncommon disorder of esophageal motility characterized by increased lower esophageal sphincter pressure and aperistalsis due to impaired cholinergic innervation. Pulmonary complications are commonly seen and include aspiration, abscess, bronchiectasis and pulmonary fibrosis. [1] Acute upper airway obstruction is another though unusual pulmonary complication, having been reported only eight times in the medical literature. [2-8] The correct diagnosis is often initially overlooked though it does have characteristic clinical and radiologic findings. We present another case and briefly review the course and treatment.

Case Report

A 65-year-old white female without previous history of pulmonary, cardiac or gastrointestinal disease presented to the Emergency Room because of acute onset of shortness of breath. She was markedly dyspneic with respiratory rate of 30 and atrial fibrillation with ventricular response of 140. She had distended neck veins and a large size cystic swelling in the midline of the neck extending from the angles of the mandible to the sternoclavicular joint and bordered laterally by the sternocleidomastoid muscles. Breath sounds were diminished but diffuse wheezing and bibasilar rales were noted. She was felt to be in severe congestive heart failure and atrial fibrillation, perhaps due to thyrotoxicosis. Admission chest x-ray (Figure) revealed an air containing structure that was to the right of the heart, separate from the trachea and extended into the neck. The lung fields had kerly B lines. Intubation was performed and digoxin and furosemide administered. Within a few hours the patient was in sinus rhythm, no respiratory distress or neck mass was present. Radiographic lung infiltrates had resolved and she was extubated. Thyroid function tests were normal. Later that day, 4 hours after dinner, she developed acute onset of dyspnea, the neck mass reappeared, following which atrial fibrillation recurred. Endotracheal intubation was performed with difficulty because of what appeared to be subglottic stenosis. Immediately afterwards her dyspnea resolved and she was extubated the following day. Prior to extubation, an NG tube was passed into the esophagus with removal of 750 cc of partially digested food. Because of clinical and radiographic suspicion of achalasia, a barium swallow was done which revealed a dilated sigmoid esophagus with a "bird's beak" appearance near the esophagogastric junction, confirming the diagnosis of achalasia. Despite the patient's denial of dysphagia she was observed to have difficulty swallowing liquids and solids. An esophagomyotomy was performed with improvement of dysphagia and no further episodes of respiratory insufficiency have occurred.

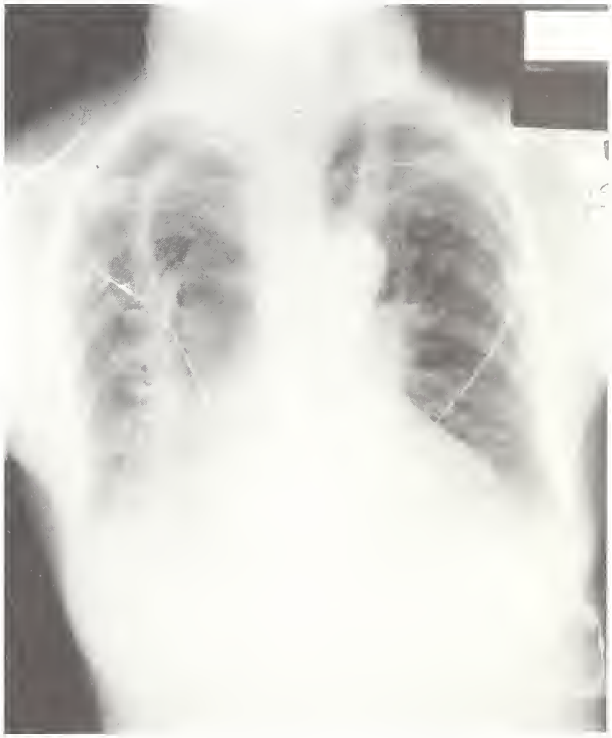

Figure 1

Admission chest radiograph showing an air containing structure in the right hemithorax. There is evidence of pulmonary congestion, more on the right.

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Discussion

First described by Bello,[2] there are now 9 cases of upper airway obstruction due to achalasia described, including the present case. Only 4 patients had a history of dysphagia[2, 4, 5, 8] and in only 2 of these was the diagnosis of achalasia previously made.[4, 5] The onset of dyspnea need not be related to recent ingestion of food. Examination often reveals stridor and in 5 of 9 cases the presence of a fluctuant neck mass which may increase in size with a Valsalva maneuver and is often mistaken for a cyst or goiter. Engorged neck veins may be present and result from either compression of the superior vena cava by the esophagus or congestive heart failure.[6] Intubation is often done with difficulty due to subglottic narrowing caused by the megaesophagus. Megaesophagus causes airway obstruction by compression of the posterior membranous portion of the trachea.[4] Brooks states that it takes less pressure to allow air passage into the esophagus, past the cricopharyngeal sphincter (15-20 cm H_2O) than to get air out (100 cm H_2O).[9] The sphincter is also incompetent because of enlarged diameter of the esophagus. It is postulated by McLean[4] that inspired air pressure would be of enough force to overcome the relatively low pressures at the cricopharyngeal sphincter but the reverse of this would not occur because of the higher expiratory pressures needed. In effect this sphincter would serve as a one way flutter valve causing progressive enlargement and anterior displacement of the esophagus and consequent tracheal compression. An alternative explanation is that the redundant distended esophagus folds back upon itself forming a "pinch cock valve."[5]

The radiologic manifestations of this patient were characteristic of others reported. The esophagus is grossly distended with air fluid level above the retained foodstuff that have a mottled appearance, and projects to the right of the mediastinum on PA view and posterior to the trachea on lateral view. These features along with the observation of the air density extending out of the thorax into the neck will assist in avoiding the misdiagnosis of abscess,[3] neoplasm or granuloma.[11]

Emergent treatment is best performed with esophagoscopy rather than blind passage of a nasogastric tube. Under certain clinical situations needle aspiration of the esophagus[7] and a relieving neck collar incision[8] have been employed with success. An esophagomyotomy is the definitive procedure as the sigmoid shaped esophagus precludes the use of pneumatic dilatation.

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Orthopaedic Management of Bone Metastases of the Proximal Femur

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Introduction

Recent advances in adjunctive chemotherapeutic agents as well as improved methods of radiation therapy have increased the survival time of patients with cancer. It has also resulted in an increased incidence of metastatic lesions. The skeletal system is the third most common site for distant metastases following the lung and liver. This has resulted in an increase in impending and pathological fractures of the skeleton.

With the mean survival time following a pathological fracture in the last decade (1970-80) significantly increased as compared to the previous decade (1960-70), the treatment of impending and pathological fractures has provided a new challenge for the orthopaedic surgeon.

The problems of metastatic lesions of the proximal femur, our largest weight bearing bone, are unfortunately well recognized. The increased biomechanical stresses located in the subtrochanteric region make this area particularly difficult to manage.

Impending and pathological subtrochanteric fractures are not amenable to fixation by the nail-plate devices.[10] The area of greatest bone destruction usually lies opposite the level of the first screw hole—the weakest portion of the side plate. This results in failure of the device. Even with methylmethacrylate filling the cortical defect, the torque and shear forces cannot be entirely relieved.[7]

This has led to our use of the Zickel Subtrochanteric Nail both with and without methylmethacrylate to stabilize both impending and pathological fractures in this area.

The Zickel Subtrochanteric Nail was designed specifically to secure both the proximal and distal fragments of subtrochanteric fractures. The Zickel Nail consists of a specially shaped medullary nail with a tunnel through its proximal part. A triflanged nail is inserted through this hole into the femoral head and neck. It is then locked in place with a set screw.

Clinical Data

A period from December 1982 through March 1985 was reviewed on the Orthopaedic Service at Bridgeport Hospital. Eight patients with a total of nine femora were involved. This series was comprised of five females and three males. The ages ranged from 52-73 years. The primary tumors were breast (2), lymphoma (2), prostate (2), lung (1), and multiple myeloma (1).

All patients underwent surgical treatment with insertion of a Zickel Subtrochanteric Nail. Adjunctive methylmethacrylate was used in five femurs. All patients underwent a course of postoperative radiation therapy.

The patients were evaluated for fracture type, relief of pain, ambulation, failure of device, failure of fixation, and surgical complications. Follow-up time ranged from 19 days to 26 months.

Results

The nine femora in our study were comprised of one pathological fracture and eight impending fractures. Average time of follow-up was 11.6 months. Five patients survived for longer than one year after the surgery.

Pain relief was evaluated by the following criteria beginning after the initial postoperative healing period. Excellent results were achieved when patients required no regular analgesics, good when occasional pain medications were needed, fair when narcotics were required to relieve pain, and poor when there was no relief of pain even with the use of narcotics.[6]

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This paper was presented at the Second CSMS Residents' Symposium on Cancer as part of the 193rd Annual Meeting of the Connecticut State Medical Society held in New Haven, CT on May 9, 1985.

Table 1

Patient	*Age*	*Sex*	*CA*	*Fracture Type*	*PMMA*	*RT*
A.D.	68	F	B	I	+	+
G.F.	64	F	LY	I	−	+
R.H.	67	M	MM	I	−	+
J.I.	59	M	L	P	−	+
N.J.	52	F	B	I	−	+
R.K.	67	F	LY	I	+	+
F.M.	73	M	P	I	+	+
			P	I	+	+
O.T.	58	F	B	I	+	+

CA – B – breast
LY – lymphoma
MM – multiple myeloma
P – prostate
L – lung
Fracture Type – I – impending
P – pathological

Two patients had excellent relief of pain. One of these patients had excellent relief of pain after both procedures. Four patients had good relief of pain. Two patients had fair relief of pain and one patient had poor relief. They are discussed later.

Five patients were full weight bearing before their lesions were discovered. Two were partial weight bearing using either crutches or a walker. At the time of identifying their lesions, the affected limb was made non-weight bearing either using crutches or by placing the patient at bedrest.

There were no failures of fixation. There were no failures of the Zickel Subtrochanteric Nail. There were no complications from the use of methylmethacrylate.

Three of the eight patients in this study have died since the time of their operative procedures. None died during the immediate postoperative period. One patient died 19 days after his procedure, one at four months, and the third 13 months after his surgery.

Two patients had extensive disease. One underwent insertion of a nail-plate device with methylmethacrylate for a pathological subtrochanteric fracture of his other hip 21 days prior to his Zickel nailing. Because of postoperative instability of this hip, he was kept at bedrest until his Zickel Nail procedure. He is the one patient who had an intraoperative complication. His impending pathological fracture was converted to an iatrogenic pathological fracture intraoperatively at the time of his Zickel nailing. This was the result of his positioning in the lateral decubitus position and the use of flexible reamers. We do not recommend either. After the Zickel nailing, he was never able to maintain a consistent level of ambulation secondary to fatigue. His activity level consisted of bed to chair transfers. He is the one patient who had poor relief of pain and was dependent on narcotics until he died 19 days after his Zickel nailing.

The other patient with extensive disease underwent a Schneider rodding of her contralateral femoral shaft one week after her Zickel nailing. She also was unable to maintain a consistent level of ambulation secondary to fatigue. Her activity consisted of short walks with a walker, but mostly transfers from bed to chair. She was able to be discharged from the hospital to Hospice where she died four months later. She had had fair relief of pain. It is interesting to note that the osteolysis of her subtrochanteric lesion persisted and eroded her lateral cortex. The Zickel Nail and adjunctive methylmethacrylate maintained a stable construct and had not failed at the time of her death.

A third patient died 13 months after his operative procedure. There were no problems with his fixation in that time period. His Zickel Nail was augmented with methylmethacrylate. He was out of bed to a chair on postoperative day number two. He was ambulating with a walker at postoperative day number six.

Discussion

This study showed that the Zickel Subtrochanteric Nail when combined with postoperative radiation therapy is an excellent device for the treatment of impending and pathological fractures of the subtrochanteric region of the femur.

When used in the proper technical manner there were no intraoperative complications. There were no applicance failures. There were no failures of fixation.

The Zickel Subtrochanteric Nail is biomechanically superior to the conventional nail-plate devices. The moment arm d on the nail-plate is greater than the moment arm d on the Zickel Subtrochanteric Nail. This results in an increased bending moment on the nail-plate. In addition, torque which is equal to F x d is greater in the nail-plate.

Through its design the Zickel Subtrochanteric Nail acts as a load sharing device. With its components, it reinforces not only the subtrochanteric region, but also the femoral shaft and the femoral neck.

Early detection of metastatic lesions in the subtrochanteric region of the femur is imperative. The ideal management of these lesions is prophylactic fixation of the impending fracture. This greatly facilitates the procedure and minimizes complications. It also allows radiation therapy to proceed without the fear of the patient sustaining a pathological fracture as he or she climbs on and off the table.

Our indications for prophylactic nailing of impending pathological fractures are based on subjective and objective criteria. Subjectively, the complaint of pain in a patient with known carcinoma is extremely important. It is our belief that this represents the presence of microfractures in the cortex. It should initiate a metastatic work-up.

Radiographically, there are well accepted criteria which are reliable in predicting the probability of a fracture through a lytic lesion. They are: 1) a lesion 2.5 cm. or

Table 2

Patient	Ambulation		Pain Relief	Fixation Failure	Complication	Duration
	Pre-Op	P-Op				
A.D.	limited	B/C	fair	–	–	4 mo.*
G.F.	pwb	fwb	good	–	–	26 mo.
R.H.	fwb	fwb	fair	–	–	13 mo.*
J.I.	pwb	B/C	poor	–	+	19 days*
N.J.	fwb	fwb	exc.	–	–	13 mo.
R.K.	fwb	fwb	good	–	–	10 mo.
F.M.	fwb	fwb	exc.	–	–	19 mo.
	fwb	fwb	exc.	–	–	18 mo.
O.T.	pwb	fwb	good	–	–	2 mo.

Ambulation – B/C – bed to chair
pwb – partial weight bearing
fwb – full weight bearing
* – expired
+ – impending converted to pathological intraop

larger involving the femur and 2) lytic destruction of 50% or more of the cortex of a long bone.[4]

We advocate the use of methylmethacrylate to insure immediate and rigid fixation.

Radiation therapy is initiated soon after fixation of the fracture. The patients in this study received their initial dose 7-10 days postoperatively. This provided adequate time for postoperative edema to subside and wound healing to begin. There were no wound complications in this group of patients.

There is no evidence that internal fixation devices or methylmethacrylate interfere with radiation therapy. Furthermore, radiation does not alter the compressive and shear strengths of methylmethacrylate.[17] It also does not alter the interface strength.[3]

Although we did not evaluate our patients for fracture healing, it does occur in the presence of methylmethacrylate. With rigid internal fixation and low dose radiation therapy (2,000-2,500 rads), pathological fracture healing following therapy has increased.[2]

Our surgical objectives include debulking the tumor and then combining the torque and shear strength of the Zickel Subtrochanteric Nail with the resistive compressive strength of methylmethacrylate to provide a stable construct. This allows us to achieve our short term goal of immediate stability of the affected limb and relief of pain. Combined with postoperative radiation therapy, physical therapy, and fracture healing, it helps us to restore limb function with a construct that will develop a fatigue life that exceeds the patient's life expectancy.

Conclusion

Impending and pathological fractures of the subtrochanteric region of the femur provide a challenging therapeutic problem for the orthopaedic surgeon. Maintenance of an aggressive multi-specialty approach to patients with these lesions is beneficial. The Zickel Subtrochanteric Nail when used in a proper technical manner can help to improve and maintain the quality of life. It helped to provide pain relief, stability, and the ability to ambulate by enabling the restoration of limb function.

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BEHIND THE FACE OF HYPERTENSION

Important Advances in Clinical Medicine

Epitomes of Progress—Internal Medicine

The Scientific Board of the California Medical Association presents the following inventory of items of progress in internal medicine. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in internal medicine that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Internal Medicine of the California Medical Association and the summaries were prepared under its direction.

Intraarterial Chemotherapy

Colorectal cancer affects 138,000 new patients and is responsible for approximately 60,000 deaths each year in the United States alone. Most patients who die of colorectal carcinoma have liver metastases, and for many the liver is the only clinical site of metastatic tumor. Chemotherapy for patients with metastatic disease consists of the fluorinated pyrimidines 5-fluorouracil (5-FU) and fluorodeoxyuridine (FUDR, or floxuridine). While 5-FU and floxuridine produce objective response rates of about 20% when given intravenously, neither has been proved to provide a survival advantage over no treatment.

A number of factors predict that 5-FU or floxuridine given via the hepatic artery may be superior to intravenous delivery in patients with liver-only metastasis from colorectal carcinoma. The blood supply of hepatic metastasis is primarily via the hepatic artery, whereas a normal liver receives a dual blood supply from the hepatic artery and portal vein. Thus, administering 5-FU or floxuridine into the hepatic artery exposes hepatic metastasis to a higher concentration of drug than normal liver tissue. Pharmacologic properties of 5-FU and floxuridine that may make hepatic artery therapy more effective include a favorable dose-response curve and high rates of first-pass hepatic extraction (80% and 95%, respectively), thus minimizing systemic toxicity. The cell-cycle phase-specific activity of 5-FU and floxuridine predicts increased cytotoxicity with long-term drug use such as is achievable with continuous infusion. The recent development of a reliable, implantable, continuous infusion pump has made hepatic artery infusion chemotherapy practicable. For these reasons, hepatic artery infusions, usually with floxuridine, have become an active area of clinical investigation.

The reported series of colorectal cancer patients treated with hepatic artery infusion have either been uncontrolled or historically controlled and are difficult to assess because they use a broad range of methods and criteria to measure response. Computed tomography, especially when done with volumetrics, is the single most objective and reliable index of disease response or progression. Radionuclide liver scans are reproducible but difficult to quantify in determining response. Although physical examination, liver enzymes and carcinoembryonic antigen levels are all unreliable methods of measuring the response of colorectal cancer metastatic to the liver, they have been used in many studies as indicators of disease response. Despite these frequently inexact methods of assessing response, the available studies of hepatic artery infusion of floxuridine have found impressive response rates ranging from 29% to 88%. In addition, some of these studies report superior durations of survival when compared with historical control groups. Whether these improved rates of response and survival are the result of variations in the tumor burden at the initiation of therapy, the methods of

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assessing response, the use of inappropriate control groups or of the efficacy of treatment is uncertain.

Hepatic artery infusion of floxuridine is associated with significant toxic effects, especially biliary sclerosis, which occurs in most patients. Recent evidence suggests that the "chemical hepatitis" reported previously may in fact have been biliary sclerosis. This is a serious toxic effect and has been documented by cholangiography, liver biopsy and at postmortem examination. It is heralded by elevation of the alkaline phosphatase level, and a doubling of the alkaline phosphatase level requires at least delaying further administration of the drug until the levels return to normal, with attenuation of further doses. The anatomic changes of biliary sclerosis are presumably not reversible and may contribute to drug-related mortality, although the associated elevations in alkaline phosphatase and bilirubin levels may resolve with the early withdrawal of therapy.

Gastric and duodenal inflammation and ulceration and cholecystitis are other complications of hepatic artery infusion of floxuridine. These complications appear to be related to the incidental perfusion of the involved organs by floxuridine. The frequency of the gastric and duodenal complications can be minimized at the time of pump implantation by ligating the gastroduodenal artery and collaterals that arise distal to the point of cannulation of the hepatic artery. Most investigators recommend routine cholecystectomy at the time of placement of the infusion pump to prevent the development of drug-induced cholecystitis.

No prospectively randomized studies comparing the efficacy and toxicity of intravenous with intraarterial administration of 5-FU or floxuridine have yet been completed. Appropriately designed, prospectively stratified, randomized trials comparing intravenous administration with hepatic artery infusion of chemotherapy for colorectal carcinoma metastatic to the liver only are in progress in the Northern California Oncology Group (headquarters in Palo Alto) and at the Memorial Sloan-Kettering Cancer Center (New York). Definitive conclusions regarding the precise role of hepatic arterial infusion chemotherapy must await the completion of these studies.

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The Routine Preoperative Chest X-ray Study

According to the report of a World Health Organization (WHO) Scientific Group, "There are some excellent studies on the futility of preoperative chest radiography," a conclusion that was reached after a comprehensive study of the relevant international medical literature. This opinion is endorsed by the Food and Drug Administration, the US Bureau of Radiological Health and most of the American specialist colleges and societies. If the results of a clinical examination are normal, no preoperative chest x-ray film is needed at any age for any surgical procedure. Moreover, even when there are clinical chest symptoms, there is little advantage to be gained in most cases because clinical judgment will decide the choice of anesthesia with as much accuracy as a chest x-ray study. Nor will postoperative management be affected by information gained from a preoperative chest film, which is not only cost-effective but increases the radiation given both to an individual patient and to the population. Indeed, it is time that the routine chest film cease to be part of a routine physicial examination, preoperatively or otherwise; the only exception may be in populations wherein chest disease is known to be prevalent.

The WHO Scientific Group on the Indications for and Limitations of Major X-Ray Diagnostic Investigations conclude that

> provided a careful clinical examination is made and there is no clinical evidence of chest disease, there is no indication for preoperative chest radiology. If the clinical examination discloses an abnormality, this in itself is not necessarily an indication for radiography. Such cases must be judged on their merits.

The available references are numerous; only a selection can be provided here.

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Fine-Needle Aspiration Biopsy of Thyroid

Thyroid nodules are common and about 4% or 40,000 per million persons in the United States have nodular goiters. Thyroid cancer, however, is rare: about 40 cases per million persons. Thus, great selectivity is necessary in deciding which nodules are likely to be malignant and to require aggressive surgical management.

Fine-needle aspiration biopsy of the thyroid has largely solved this dilemma. Introduced by Soderstrom in 1952, it has been used widely in Sweden, Europe and Japan. Only in the past ten years, however, with the development of a cadre of trained cytologists, has fine-needle aspiration biopsy been widely used in the United States.

Fine-needle aspiration biopsy of the thyroid is a simple office procedure, nontraumatic, acceptable to patients and easily repeated if necessary. If the aspirate is diluted with blood, or not enough thyroid tissue is obtained, it must be repeated. Other than an occasional tiny hematoma at the site of aspiration, there have been no complications. There has been no spread of cancer with this technique.

A physician will usually receive one of three reports from the cytologist: (1) clearly malignant, (2) clearly benign or (3) follicular neoplasm or suspicious for neoplasm.

Papillary, medullary, anaplastic and metastatic neoplasms are easily diagnosed and, if present, require surgical confirmation and appropriate therapy. Clearly benign lesions include involutionary nodules, benign thyroid nodules, chronic lymphocytic thyroiditis (Hashimoto's thyroiditis), subacute thyroiditis and multinodular goiter. Patients with these lesions are usually treated with levothyroxine to suppress thyroid-stimulating hormone and growth. Follicular neoplasms are usually benign (about 85%) but occasionally malignant (15%). If the lesion is large (more than 2 cm), firm or has shown recent growth, it should be surgically removed. If it is small and soft, the patient can be given a trial of thyroxine therapy for three to six months. If the lesion fails to regress or grows, then it should be removed. Cysts of the thyroid can easily be evacuated by this technique and they are rarely malignant (less than 5%). Malignant lesions will usually recur, with bloody fluid and evidence of internal echos on ultrasound scan. If thyroid cysts do recur after two or three aspirations, they probably should be surgically removed.

False-positive results—that is, a diagnosis of cancer in a benign lesion—occur in about 4% of aspirations, and false-negatives—that is, a diagnosis of a benign lesion in the presence of malignancy—in about the same percentage. Thus, the method is both sensitive and specific. Note that fine-needle aspiration biopsy can be used in the diagnosis of other neck masses, such as metastatic cancer of Hodgkin's disease.

Fine-needle aspiration biopsy of the thyroid is probably the most important advance in the management of thyroid nodules in the past decade. It has enabled physicians to avoid delay in the diagnosis of thyroid malignancy and to avoid an unnecessary operation for benign thyroid lesions. As the initial screening test, it will reduce by half the cost of evaluating a thyroid nodule.

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New Criteria for the Diagnosis of Alzheimer's Disease

With the increased publicity concerning Alzheimer's disease, the development of state initiatives for diagnosing and treating cases of Alzheimer's and the appearance on the horizon of a number of experimental therapies, the accurate diagnosis of this disorder becomes important. Unfortunately, there is no biochemical or radiographic marker upon which a clinician can rely. In 1980, the American Psychiatric Association in the third edition of its *Diagnostic and Statistical Manual* (DSM-III) proposed criteria that have been widely accepted for the clinical diagnosis of Alzheimer's disease. However, these criteria have been found to apply to only about half of the Alzheimer patients because the disease presents in a greater variety of ways than first believed. Thus, under DSM-III criteria, a patient with Alzheimer's disease was required to have impairment not only of memory, but of at least one other area of cognition; the course was decribed as having an insidious onset with a steady progression, and, most important, other neurologic or systemic disorders that can produce dementia had to be excluded.

In reality, it has been found that in some patients, Alzheimer's disease may begin primarily as a memory, language or constructional deficit that may progress for several years before becoming more generalized. The course is always one of deterioration, but in some patients it may be interrupted by plateaus lasting for several years.

Particularly in older patients with Alzheimer's disease, the coincidence of an Alzheimer process with a single stroke, with thyroid disturbance, vitamin B_{12} deficiency and so forth, may occur. To account for these deviations and to provide a wider umbrella for physicians, a work group under the auspices of the Department of Health and Human Services Task Force in Alzheimer's Disease arrived at the following recommendations:

1. A diagnosis of *definite* Alzheimer's disease requires clinical criteria for probable Alzheimer's disease and histopathologic evidence obtained from a biopsy or autopsy.
2. The criteria for a clinical diagnosis of *probable* Alzheimer's disease are similar to those of the original DSM-III and include the following:

- There must be a dementia established by clinical examination and documented by a mental state test that includes deficits in two or more areas of cognition;
- There should be progressive worsening of memory and other cognitive functions;
- No disturbances of consciousness;
- The absence of systemic disorders or other brain diseases that, among themselves, could account for progressive deficits.

This diagnosis of probable Alzheimer's disease is similar to that originally described in DSM-III.

Critical to the diagnosis of dementia is the documentation of the cognitive deficit by the use of mental state tests such as the Mini-Mental Test or a similar examination. The importance of tests of mental state is emphasized because patients with dementia early in the course of their disorder may maintain good social conversation and may not be obviously demented during routine history taking. Laboratory features consistent with a diagnosis of probable Alzheimer's disease include a computed tomographic scan normal for age or with evidence of cerebral atrophy, a normal electroencephalogram or one with increased slow-wave activity and normal findings on a lumbar puncture. Often there is a family history of similar disorders. As the disease progresses, there is impairment of activities of daily living and altered patterns of behavior. There may be associated symptoms of depression and decreased cognizance, delusions, hallucination, verbal or physical outbursts, sexual disorders and weight loss. Usually there are no focal neurologic findings such as hemiparesis, sensory loss, visual field deficits or incoordination early in the course of Alzheimer's disease.

A third category of diagnosis is that of *possible* Alzheimer's disease. This category includes patients who have a progressive dementia but have either a variation in the onset, presentation or clinical course or a systemic or brain disorder that is enough to produce dementia, but it is not considered to be the cause of dementia because, when treated, the dementia continues to progress. Among the variations of onset is a subgroup of patients who present with a progressive deterioration in a single area of cognitive function, such as aphasia, apraxia or agnosia, or a pure memory deficit for several years before the development of a more generalized disorder. Such patients, however, must be investigated for the possibility of focal neurologic disease.

These criteria emphasize both the normal history and progression seen in patients with Alzheimer's disease and the continued need to exclude other disorders that may produce a dementia syndrome. Among the more common disorders that must be excluded are multi-infarct dementia, bipolar depressive disorders and drug intoxications. Other disorders that may occur and produce dementia include thyroid disease, pernicious anemia, neurosyphilis, Creutzfeldt-Jakob disease, subdural hematoma, normal pressure hydrocephalus, Huntington's disease and a brain tumor. The workup of a patient with Alzheimer's disease requires an accurate medical history, neurologic, psychiatric and clinical examinations and laboratory studies to exclude these other diagnoses. Wide-spread adoption of these recommended criteria for the clinical diagnosis of Alzheimer's disease would lead to improved communication among the physicians caring for patients with this devastating disorder.

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Clinical Use of Platelet-Suppressant Drugs

Aspirin, by inhibiting cyclooxygenase, blocks the formation by the platelet of thrómboxane A_2, the most powerful natural potentiator of platelet aggregation. The effect is prolonged, probably for the life span of the platelet, and can be shown in vivo by a prolonged bleeding time. As cyclooxygenase is required also by endothelial cells to form prostacyclin, which inhibits platelet aggregation, there has been some concern that the overall effect of aspirin might not be to reduce arterial thromboembolism. There have been many clinical trials with aspirin and other drugs that interfere with platelet function and analysis of these as a group allows us to make some clinical recommendations.

Aspirin can reduce (by about 5% in the first year) the risk of sudden death and of myocardial infarction in persons with a high risk of these incidents, namely, those who have had a recent transient ischemic attack or myocardial infarction or who have unstable angina. In two studies the frequency of coronary artery bypass graft occlusion was reduced by aspirin therapy initiated shortly before or immediately after an operation. There is also evidence that aspirin reduces the risk of stroke and sudden death following a transient ischemic attack and that it is effective in preventing thromboembolic complications in patients with essential thrombocythemia and polycythemia and the occlusion of arteriovenous shunts. The studies as a whole show a significant reduction in morbidity for men only because the number of women studied was too small, but there is no known pharmacologic or physiologic reason why the effect should be sex-dependent. The benefit is greater the earlier the aspirin therapy is started and is apparent within the dose range of 100 to 1,000 mg a day. Aspirin is contraindicated in those with other acquired or inherited hemostatic deficiencies, in patients with significant dyspepsia or with previous gastrointestinal bleeding; these considerations will exclude about 10% of otherwise suitable patients.

Although a beneficial trend has been noted in the trials of sulfinpyrazone in patients with transient ischemic attacks, the results are not statistically significant, and neither this drug nor dipyridamole can yet be recommended for routine use either alone or combined with aspirin. There is no indication for using aspirin to prevent embolization from prosthetic heart valves, for which anticoagulants remain the first line of therapy, with sulfinpyrazone giving added benefit.

Many questions remain to be answered, including the most effective dose of aspirin, the duration of treatment, the role of combination therapy with other platelet-function-altering drugs and the evaluation of new drugs, particularly ticlopidine hydrochloride, pentoxifylline and ketanserin. Clinical trials designed to study these matters are in progress and their results are eagerly awaited.

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Adjuvant Chemotherapy for Breast Cancer

Stage I (T_1,N_0,M_0) and stage II (T_1,N_1,M_0, $T_2,N_{0\text{-}1},M_0$) breast cancers are potentially curable with local-regional therapy. The risk of recurrence, usually at distant sites, after such therapy is also known. The cause of recurrent disease is microscopic metastatic tumor already present but not identifiable at the time of the initial operation. Given these conditions, administering systemic antitumor therapy as an additional (adjuvant) treatment to eradicate residual tumor, after definitive local-regional therapy, is a rational approach.

Over the past 15 years, dozens of adjuvant therapy trials in breast cancer have been devised and patient accession completed, and the data examined and reexamined for statistical significance and clinical implications. The adjuvant treatments have ranged from two- to five-day courses of a single chemotherapy agent given immediately after surgical treatment, to multidrug chemohormonal therapy combinations given for two years. The early trials concentrated on women with involved axillary nodes (N_1) who were at high risk for recurrence. More recently, node-negative trials have also been initiated. Data analysis has been exhaustive. Updates have been frequently presented and regularly published. Prognostic subgroups have been studied—premenopausal and postmenopausal women, patients with one to three positive nodes versus those with four or more nodes involved, or four to ten nodes versus more than ten nodes. Explanations for the various results seen in different subgroups abound.

Two important benefits may accrue from adjuvant chemotherapy: Improved overall survival is the primary possible benefit of adjuvant treatment and is the one ultimately sought. However, prolonged relapse-free survival may also be worthwhile. Enhanced relapse-free survival and even improved overall survival must be weighed against possible toxicity, monetary costs and effect on lifestyle in finally deciding the value of adjuvant therapy as standard care. Therefore, until long-term data are available and a beneficial impact is clear, adjuvant programs should remain within the realm of experimental therapy.

In premenopausal women with metastasis to nodes, numerous studies show significantly prolonged relapse-free survival and some show an overall survival benefit after adjuvant chemotherapy. While single-drug trials show such benefits in some premenopausal subsets, the multidrug adjuvant programs of Bonadonna and co-workers with CMF (cyclophosphamide, methotrexate and 5-fluorouracil), now reported with a ten-year median follow-up, appear broadly efficacious among premenopausal patients. The optimal duration of treatment is under study. In one controlled trial, 6 months of CMF therapy were as good as 12 months. Even shorter programs of more intense therapy may eventually be found to be equally or more useful. Therefore, while giving multidrug adjuvant chemotherapy to node-positive, premenopausal women has achieved the status of "conventional" or "standard" treatment, research trials to further define optimal drugs and treatment schedules are in order. These new trials will not include a "no-treatment" control group.

Data on the efficacy of adjuvant therapy using drugs, hormones or a combination of both for postmenopausal women with involved axillary nodes (N_1) are widely available. A few studies have shown clear benefit, with enhanced relapse-free and overall survival. Others show enhanced relapse-free survival without concomitant overall survival advantage. Still others—slightly more than half of all reported—show no benefit on either count. Some investigators have emphasized the need to give full-dose adjuvant chemotherapy to postmenopausal women to obtain beneficial results. Others, concerned with the toxicity of adjuvant chemotherapy in older patients, have turned to trials of adjuvant hormonal therapies.

The available data stimulate controversy about the place of adjuvant therapy in the management of postmenopausal women with positive nodes. It seems inappropriate to present adjuvant multiagent chemotherapy as "standard" for postmenopausal women based on the evidence of clinical trials thus far. However, enough positive data are available to demand further evaluation of various adjuvant approaches using the mechanism of well-designed, large-scale, cooperative clincial trials. Questions of dose, duration, amount, nature and timing of treatment all warrant investigation. Clinical trials evaluating such issues in node-positive postmenopausal women should ideally include a no-treatment control group, though this issue of study design is highly controversial in and of itself.

Adjuvant therapy for breast cancer has had an important, beneficial impact, especially in premenopausal women with metastasis to nodes. Clearly, however, we are far from having all the answers. Continued commitment among physicians to participate in well-designed trials that both ask important questions and offer the most advanced patient care is crucial. With the strong support of the medical community to continue careful adjuvant therapy trials in breast cancer, the uncertainties extant in the field today should give way to further positive directions over the next several years.

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Cyclosporine—A Powerful New Immunosuppressant

Cyclosporine is a powerful immunosuppressive drug that has had a major impact on the success of organ transplantation since its introduction a few years ago. It has a unique cyclic endecapeptide structure, which inhibits T-cell activation, without directly affecting B cells, macrophages or any other branch of the immune responses. Unlike its predecessor, azathioprine, cyclosporine has not thus far provided toxic to rapidly proliferating cells such as bone marrow. A further advantage of cyclosporine therapy is the reduced or eliminated requirement for prolonged administration of high-dose corticosteroids, with a resultant improvement in the quality of life for transplant recipients. An unexpected benefit has been a shorter hospital stay and a reduction in the cost of transplantation by as much as 30%.

Cyclosporine use has improved the one-year survival rate of cadaveric renal allografts from 50% to as high as 85%. Similarly, the one-year survival rate of heart transplant recipients has increased from about 60% to 80%. The one-year survival rate of liver transplant recipients has almost doubled, to 70% for children and 50% for adults. Clinical heart and lung transplantation, which was never done successfully before cyclosporine, has now been carried out in more than 20 patients, with a number of long-term survivors. A survival advantage in pancreas and bone marrow transplant patients treated with cyclosporine has not been clearly shown, though it does lower the incidence and severity of graft-versus-host disease. Because of its powerful immunosuppressive properties, the use of cyclosporine is being considered in a number of diseases with purported immune mechanisms. A successful trial of cyclosporine in abolishing insulin requirements among patients with type I diabetes mellitus was recently reported.

Cyclosporine has a number of clinically mild side effects including hirsutism, gingival hyperplasia, nausea and elevated liver enzyme values. In rare cases, there is also central nervous system toxicity including ataxia, quadriparesis, changes in mental state and aseptic meningitis. The incidence of opportunistic infections is similar to that of azathioprine-treated patients, although their severity appears to be reduced. Lymphoproliferative malignant disorders initially appeared to be increased among cyclosporine users but recent experience is reassuring. These B-cell tumors appear to follow reactivation of or infection with Epstein-Barr virus (EBV) and contain the Epstein-Barr nuclear antigen (EBNA) or portions of the EBV genome. These tumors may represent uncontrolled proliferation of virally transformed lymphocytes and respond temporarily to the antiviral agent acyclovir. Reducing or eliminating immunosuppression has also been followed by remission of tumor, albeit associated with graft rejection.

The most serious common side effect of cyclosporine is its nephrotoxicity. In as many as 80% of recipients a significant rise in the serum creatinine level occurs. This appears to involve both glomerular and tubular damage, and it is at least partly dose-dependent. Though renal insufficiency can often be minimized by reducing the dose or by switching the therapy to azathioprine, many patients will have irreversible renal damage and a few require dialysis. Cyclosporine nephrotoxicity is a problem in renal transplantation because it cannot be easily distinguished from graft rejection; it is especially worrisome in heart and liver transplant recipients, in whom reduction of immunosuppression and subsequent graft rejection may result in death. The renal lesion is accompanied by hypertension, which is often very difficult to control.

Cyclosporine has had a favorable impact on the field of organ transplantation, but its long-term utility may be limited or negated by its nephrotoxicity. Clinical studies are currently being done to define the precise role of cyclosporine in organ transplantation. Obviously, caution must be exerted in using this substance in any condition, including diabetes, where morbidity and mortality may be determined by renal function.

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Non-A, Non-B Hepatitis

The ability to diagnose hepatitis A, hepatitis B, δ-agent, cytomegalovirus and Epstein-Barr virus infections through specific serologic tests has uncovered a series of patients in whom syndromes develop that resemble viral hepatitis but serologic test results do not suggest the above illnesses. These patients have a condition currently known as non-A, non-B hepatitis, which is responsible for about 90% of cases of posttransfusion hepatitis and 25% of sporadic cases of hepatitis in the United States. Studies of outbreaks in communities or hospital facilities of many episodes of viral hepatitis in humans and chimpanzees and of repeated inoculations of chimpanzees and marmosets with infectious serum have established the existence of more than one agent responsible for this illness. At least one of the agents appears to be waterborne, spread by the fecal-oral route and does not lead to a carrier state. Current interest in discovering the etiology of non-A, non-B hepatitis is reflected by the many reports identifying agents possibly related to this illness. These include reverse transcriptase activity in plasma products and human serum specimens from cases of posttransfusion hepatitis, 27-nm viruslike particles in stool specimens of Nepalese patients with epidemic non-A, non-B hepatitis and marmosets infected with their serum, a putative antigen by immunocytochemical staining in the liver of a chimpanzee with acute non-A, non-B hepatitis and isolation of an 85- to 90-nm membrane-coated virus from chimpanzee liver cultures inoculated with serum from patients with posttransfusion hepatitis. Other investigators have repeatedly detected hepatitis B viral DNA and hepatitis B surface antigen by radioimmunoassay using monoclonal antibodies in non-A, non-B carrier livers or serum specimens. Whether non-A, non-B infection will eventually prove to be due to any of these agents is still open to independent confirmation of these findings.

Non-A, non-B hepatitis should be looked for in patients with sporadic or posttransfusion acute or chronic hepatitis in whom laboratory tests rule out the viral illness previously mentioned. Other conditions to investigate depend on the clinical setting and may include infections (δ-agent, herpes simplex, syphilis, toxoplasmosis, brucellosis, Q fever), metabolic disorders (Wilson's disease, hemachromatosis, fatty liver), biliary tract disease, hemodynamic insults to the liver, drug-induced liver disease and idiopathic chronic active hepatitis.

The clinical course of non-A, non-B hepatitis is variable and may depend on the nature of the responsible agent, the vehicle or route of administration and host factors not yet characterized. Although most cases of posttransfusion acute non-A, non-B hepatitis are clinically silent, this illness causes as many cases of fulminant hepatitis in the United States as does hepatitis B. Posttransfusion non-A, non-B hepatitis leads to serious chronic liver disease (chronic active hepatitis or cirrhosis) in as many as 60% of cases in some series. Primary hepatocellular carcinoma has been described in patients whose only risk factor appears to be posttransfusion non-A, non-B hepatitis.

It is unclear whether this illness can be prevented by administering immune globulin before or after exposure. In a trial of immune serum globulin (ISG) in 175 patients undergoing a cardiovascular surgical procedure, the incidence of posttransfusion hepatitis in treatment and control groups was the same. In a randomized, placebo-controlled trial of hepatitis B immune globulin (HBIG) and ISG in 279 cardiac operation patients, recipients of either globulin preparation had a lower incidence of icteric non-A, non-B hepatitis (1.1% versus 7.4%) and fewer patients progressed to chronic liver disease (0.5% versus 10%). In a similar trial of ISG in posttransfusion prophylaxis of 2,204 patients, ISG reduced the incidence of icteric hepatitis (0.8% versus 1.8%) but not anicteric cases (7.7% versus 6.9%). The biggest reduction in posttransfusion hepatitis in this study was achieved not by ISG treatment but by the use of noncommercial blood (2 cases in 775 recipients of volunteer blood, both in the ISG group). The results of these trials are not easily compared because the globulin preparations, source of blood transfused and recipients of blood products were different. The studies taken as a group, however, suggest that the exclusive use of volunteer blood may be the most useful measure to prevent posttransfusion hepatitis. Others have shown that serum alanine aminotransferase (ALT) or anti-hepatitis B core antibody (anti-HBc) testing of blood donors and rejection of blood units with elevated ALT or anti-HBc levels may decrease the incidence of posttransfusion hepatitis in recipients. Whether or not immune globulin administration or any other measure can reduce the incidence of hepatitis after transfusion of volunteer blood with normal ALT levels and absent anti-HBc remains to be proved. To date, blood banks have not adopted a policy of screening for these serologic markers epidemiologically associated with non-A, non-B hepatitis infectivity. A recent randomized, placebo-controlled trial of HBIG versus placebo in hemodialysis patients has shown prevention of non-A, non-B hepatitis during but not after administration of HBIG, suggesting that protection was passive and no active immunization occurred.

Treatment studies in this illness continue to be hampered by the lack of reliable diagnostic tests. An unknown number of cases of posttransfusion non-A, non-B hepatitis have been included in trials of corticosteroids in treating chronic active hepatitis. The proper management of chronic active non-A, non-B hepatitis may include a trial of prednisone if the illness is symptomatic, serum aminotransferase and globulin levels are moderately to greatly elevated and a liver biopsy specimen shows severe active liver disease. At Stanford University Medical Center we are currently enrolling patients in a pilot study of human leukocyte interferon for treating patients with posttransfusion non-A, non-B chronic active hepatitis.

Identifying the agent of non-A, non-B hepatitis and developing reliable diagnostic laboratory tests for its detection will allow rigorous reexamination of the data summarized above. A better understanding of the natural history and transmissibility of non-A, non-B hepatitis will then allow a rational approach to its treatment and prevention.

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New Antibiotics

Several new antibiotics entered into clinical practice in 1984 and the role of the third-generation cephalosporins was better defined. Although the latter antibiotics are costly, they have several advantages over first- or second-generation cephalosporins and a very competitive race has ensued between cefotaxime, moxalactam, ceftizoxime, ceftazidime and cefoperazone. These agents are frequently used in the empiric treatment of patients with infections like bacterial sepsis, bacillary meningitis or pneumonia before the cause is identified by laboratory studies. Physicians often substitute these compounds for aminoglycosides such as tobramycin and gentamicin to avoid nephrotoxicity. This is particularly the case in infections such as septicemia and community-acquired pneumonia in immunocompromised patients.

Another new antibiotic is a combination of clavulanic acid with ampicillin. The former compound binds β-lactamases of Gram-positive and Gram-negative bacteria, thus allowing ampicillin to penetrate bacterial cells before it is destroyed. Organisms frequently resistant to ampicillin such as *Staphylococcus aureus*, *Klebsiella* and other Gram-negative bacilli are now sensitive. This compound is taken orally and can be used in treating complicated outpatient infections. We are also looking with interest at a new class of antibiotics known as the quinolines (pyridonecarboxylic acid compounds) which are derived from nalidixic acid. Such agents include ciprofloxacin, norfloxacin and enoxacin and have a broad range of antibacterial activity against both Gram-positive and Gram-negative bacteria. The bottom line is that a physician who practices primarily in the outpatient arena will have several new compounds effective against complicated infections and that will shorten hospital stays.

The concept of diagnosis-related groups (DRGs) and its inherent logic that dictates reimbursing hospitals is also having an effect on antibiotic prescriptions. Hospitals are looking to their pharmacies to provide tighter guidelines for the use of antibiotics, as they often account for 20% to 30% of all pharmacy purchase costs. New ways are also being developed to treat morbid infections in the outpatient clinical area and thus decrease the duration of hospital stay for patients who have resolving infections such as osteomyelitis, abdominal abscess, pneumonia, empyema and even endocarditis. Infusion centers exist where patients can receive on a daily outpatient basis antibiotics via Hickman lines or catheters in peripheral veins with "heparin locks." Another approach is to employ nurses to visit the homes of patients to administer antibiotics daily. Antibiotic costs will probably gain in importance as a deciding factor in their use.

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Calcium Channel Blockers

Calcium channel blocking agents are important new drugs used in treating coronary and other cardiac diseases. The currently available drugs, diltiazem hydrochloride, nifedipine and verapamil, have been effective in treating coronary artery spasm, and their use in the management of angina and supraventricular arrhythmias has been well documented. The ability of these agents to prevent or relieve spasm theoretically makes them ideal for use in treating other smooth muscle disorders. Although the three available drugs all inhibit the entrance of calcium into cells, they are different compounds and vary in their clinical effect. Nifedipine is a stronger peripheral vasodilator, verapamil causes more myocardial depression and diltiazem and verapamil affect the sinoatrial and atrioventricular nodes. Consideration of these factors is important in choosing which drug will be used, either alone or combined with other drugs such as β-blockers or nitrates.

Several clinical trials have shown the effectiveness of these drugs in treating systemic hypertension, often used as monotherapy. Nifedipine has been extensively studied and may be more beneficial due to its more potent peripheral vasodilating property, and it is very effective in managing cases of hypertensive crisis. Verapamil and diltiazem are also effective in treating hypertension and it is felt by some that they may be more suitable for long-term treatment because nifedipine is more likely to lead to reflex activation of the sympathetic nervous system.

The use of calcium channel blocking drugs in the treatment of pulmonary hypertension is encouraging. All three drugs have reduced pulmonary artery pressure and pulmonary vascular resistance in patients with primary pulmonary hypertension and some types of secondary pulmonary hypertension. However, the response to calcium entry blocking agents in patients with precapillary pulmonary hypertension is unpredictable and the drugs may sometimes produce deleterious effects.

Active clinical investigation is continuing in the use of calcium channel blockers for other conditions, including congestive heart failure, hypertrophic cardiomyopathy, myocardial preservation, bronchial asthma, Raynaud's phenomenon, migraine headache, cerebrovascular spasm, cerebral ischemia, premature labor and disorders of esophageal motility. Calcium channel blockers will likely be increasingly used in smooth muscle disorders, especially as new drugs become available that are more specific for certain types of smooth muscle.

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The Protein C Anticoagulant Pathway and Thrombosis

Proteins C and S are recently discovered vitamin K-dependent proteins that unlike the other vitamin K-dependent clotting factors—II, VII, IX and X—act as physiologic anticoagulants rather than procoagulants. Activated protein C inhibits coagulation by destroying activated factors V and VIII; protein S is an essential cofactor in the expression of protein C's anticoagulant activity. Protein C circulates in an inactive zymogen form and is activated by thrombin bound to an endothelial-cell surface protein, thrombomodulin. Activated protein C may also have a stimulatory effect on fibrinolysis. The protein C anticoagulant pathway thus provides a mechanism whereby formation of thrombin is accompanied by generation of anticoagulant and profibrinolytic activity, limiting fibrin formation to areas of local vascular damage.

Hereditary deficiencies of the protein C anticoagulant mechanism are associated with venous thromboembolic disease. Heterozygous protein C-deficient persons have about half the normal amount of protein C. Many but not all manifest recurrent episodes of thrombophlebitis, pulmonary embolism or both, beginning after the first decade of life, often associated with a precipitating event such as trauma or an operation. Administering heparin or warfarin is effective. Warfarin therapy reduces the levels of all vitamin K-dependent proteins, but protein C levels fall faster than levels of factors II, IX and X. Therefore initiating warfarin therapy, especially with loading doses, may create a brief period of increased vulnerability to thrombosis, including the rare syndrome of dermal thrombosis with necrosis ("warfarin skin necrosis"). Such complications can be avoided by continuing a regimen of heparin for several days, until full oral anticoagulation has occurred.

Homozygous protein C deficiency has been described in several newborns, who have little or no detectable protein C and who show dramatic, life-threatening thrombotic complications, including purpura fulminans, a necrotic dermal thrombotic lesion closely resembling warfarin skin necrosis. Constant protein C repletion with prothrombin complex concentrate is the only effective therapy so far described; however, this therapy is associated with a risk of transmitting hepatitis. Acquired deficiency of protein C is seen in cases of disseminated intravascular coagulation, liver disease, vitamin K deficiency and warfarin therapy; the clinical consequences of such deficiency states are not well established.

A diagnosis of protein C deficiency is best made with one of the recently described functional assays, as normal levels of a functionally defective molecule will not be detected by antigenic assays. Its diagnosis in a patient receiving warfarin requires finding a disproportionately low protein C level when compared with that of another vitamin K-dependent protein, such as factor II, VII or X.

Partial or complete protein S deficiency causes a tendency to venous thromboembolic disease very similar to that of heterozygous protein C deficiency. The use of warfarin or heparin is effective treatment. Neither protein C nor protein S deficiency has been clearly shown to increase the risk of arterial thromboembolism. A search for other defects in the protein C anticoagulant pathway, such as quantitative or qualitative deficiencies of thrombomodulin, is under way in many laboratories and may further increase our understanding of the pathophysiology of thromboembolic disease.

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Antibody Testing for the AIDS Retrovirus—Implications for Clinicians

A new human retrovirus (variously called LAV, HTLV-III or ARV) has been isolated from tissues of patients with acquired immunodeficiency syndrome (AIDS) and with lymphadenopathy in both Europe and the United States. Antibodies against this virus have been detected in a high percentage of AIDS patients, asymptomatic homosexual men and men with hemophilia. Investigations of blood donors implicated as the source of transfusion-acquired AIDS suggest that there may be a prolonged asymptomatic period of infectivity. Testing of all blood donors for antibody to the AIDS retrovirus ARV) may soon be required. Enzyme-linked immunosorbent assays (ELISA) for ARV antibody will be used to screen blood units and those found to have the antibody will be discarded. This measures appears both practical and reasonable as a means of preventing future cases of transfusion-acquired AIDS.

The availability of this test will create several problems for practicing clinicians. First, positive tests will be found in persons not in any group known to be at risk for AIDS. Many of these ELISA results will be false-positive. Because confirmatory tests such as Western blotting or immunofluorescence are expensive, technically demanding, not widely available and of uncertain sensitivity, it will be difficult initially to determine which positive results reflect possible infectivity for others or an increased risk of AIDS developing. Despite this uncertainty, persons with repeatedly positive tests should be notified because they can take actions to reduce potential spread of the virus via sexual contact, child bearing or nonsexual transfer of body fluids.

The notification of a positive test result will have enormous emotional impact on most persons and requires that physicians be well informed about the limitations of the tests and implications of the results. Even if systems are developed to inform persons of their results through public agencies, many will seek reassurance and follow-up from their personal physicians.

The second problem for clinicians will be the skillful use of these tests for diagnosis. Because of the wide spectrum of clinical manifestations of AIDS-retrovirus infections and the high prevalence of the AIDS-retrovirus antibody in groups at high risk for AIDS, the diagnostic usefulness of finding the antibody in high-risk patients with unusual clinical syndromes will be limited. For example, should a gay man with idiopathic Bell's palsy or thrombocytopenia and a test positive for AIDS-retrovirus antibody be diagnosed as having an ARV-associated condition? While these tests will help to expand knowledge of the clinical spectrum of AIDS-retrovirus infections, they may also be confusing and misleading.

One possible solution to these problems is the development of tests to detect the AIDS virus directly in blood and tissues. This may be accomplished by growing retroviruses in cultures or detecting virus-specific antigens or nucleic acids. These techniques eventually may replace the soon-to-be released antibody assays. In the meantime, physicians will be faced with the difficult task of explaining and interpreting a test of uncertain significance to anxious patients.

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New Antiarrhythmic Agents—Amiodarone, Mexiletine, Tocainide

Until recently, antiarrhythmic drug therapy has been restricted to a few agents. Over the past decade, however, there has been a dramatic increase in the number of agents that have been or are soon to be released for clinical use. One drug, tocainide, has just been released for clinical use and two others—amiodarone and mexiletine—are subject to intensive clinical investigation.

Amiodarone

Amiodarone, an agent that prolongs myocardial refractoriness in almost all types of cardiac cells, is quite effective in the clinical management of supraventricular and ventricular arrhythmias and arrhythmias associated with the Wolff-Parkinson-White syndrome. In numerous clinical trials amiodarone effectively suppressed these arrhythmias in patients who did not respond to conventional antiarrhythmic drug therapy. There appears to be general agreement that it requires days, sometimes weeks or even, rarely, months for the full antiarrhythmic efficacy of oral administration of amiodarone to become manifest. There still exists some controversy regarding amiodarone's antiarrhythmic efficacy when given intravenously. The drug is most commonly given orally, usually with a loading dose of 800 to 1,800 mg a day during the first week, followed by a daily maintenance dose of 200 to 800 mg a day. Amiodarone seems to be well tolerated by most patients, but the increasing use of this drug, several unwanted side effects have been recognized. A small percentage ($\leq 10\%$) of patients have to stop taking amiodarone because of more serious and even life-threatening side effects. These include refractory heart failure; pulmonary fibrosis; central nervous system side effects such as tremor, ataxia, paresthesia, headache and nightmare; sinus arrest, and exacerbation of ventricular tachycardia. Less alarming side effects include corneal microdeposits, with possible association of photophobia, thyroid dysfunction (hypothyroidism or hyperthyroidism), a peculiar bluish or slate-gray discoloration of the skin including the face and abnormalities on liver function tests. These complications may take several weeks or even months to disappear after the drug regimen is discontinued. Many investigators, therefore, have suggested that this drug be used only in patients with serious arrhythmias unresponsive to routine therapy.

Mexiletine

Mexiletine is a structural analog of lidocaine that, however, is effective given orally. The oral dose ranges from 100 to 400 mg every six to eight hours. For urgent therapy, the intravenous route may be considered, with 200 to 250 mg given over five minutes, followed by an infusion of 60 to 90 mg an hour. Mexiletine is effective in suppressing ventricular arrhythmias; its definite role in the control of these arrhythmias, however, is still not defined. Most of the side effects occur during the initial period of therapy and later disappear in most patients during maintenance therapy. The side effects are frequently of central nervous system origin, including tremor, nystagmus, diplopia, dizziness, dysarthria, paresthesia, ataxia and confusion. Gastrointestional side effects are common and include nausea, vomiting and dyspepsia. Thrombocytopenia and the presence of antinuclear antibody rarely occur but have been reported in some cases. Side effects are more likely to occur at plasma concentrations of greater than 1.5 to 2μg per ml, which is very close to the therapeutic level. Cardiovascular effects of mexiletine are infrequent and include hypotension, bradycardia and exacerbation of arrhythmias. Mexiletine is generally well tolerated, however.

Tocainide

Tocainide is another structural analog of lidocaine and is, like mexiletine, effective against ventricular arrhythmias when given orally. Both tocainide and mexiletine have relatively long half-lives (12 hours).

In a number of clinical studies, tocainide has decreased the frequency of ventricular premature depolarizations, with variable side effects on ventricular tachycardia. The precise role of tocainide and the clinical setting in which the drug may eventually be used is still not defined. It would appear that tocainide will exert its antiarrhythmic efficacy at plasma concentrations above 6 μg per ml. The oral dosage regimen for tocainide is usually 400 to 600 mg every eight hours. Tocainide is generally well tolerated. Side effects include central nervous system disorders such as tremor, headache, sweating, altered hearing, dizziness, nervousness, hot flashes, paresthesia, blurred vision or diplopia, anxiety and lightheadedness. Gastrointestinal complaints, however, are more common and include anorexia, vomiting, nausea, abdominal pain and constipation.

These three antiarrhythmic agents hold the potential for dramatically increasing a clinician's ability to control serious cardiac arrhythmias. However, with their use comes the additional problem of serious side effects that must be carefully monitored by the physician.

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Clinical Use of Portable Insulin Pumps

An array of evidence supports the view that diabetic complications are attributable to the metabolic derangements caused by elevated blood glucose levels. This concept has been translated to patient care—thus the increased emphasis on blood glucose control. Ideally, changes in blood glucose levels would automatically be sensed and insulin appropriately released into the portal circulation. This could be accomplished with pancreatic islet cell transplantation or by an implantable glucose-controlled ("closed loop") insulin infusion system, a so-called artificial pancreas. While research into these areas continues, the development of blood glucose self-monitoring and patient-controlled external medication infusion pumps permitted clinical trials and now general clinical use of "open-loop" continuous subcutaneous insulin infusion (CSII) systems.

These insulin infusion devices, which use only short-acting insulin, consist of a syringe or an insulin reservoir in conjunction with a battery-operated pump controlled by an electronic mechanism that is designed for a relatively continuous infusion rate of insulin, the basal rate. This basal rate is supplemented by an increase in the insulin infusion rate controlled manually by the patient at mealtimes, the meal bolus. Patients must regularly—at least three to four times a day—monitor capillary blood glucose responses to the insulin infusion to insure adequate insulin doses. The insulin is delivered through disposable plastic tubing and a subcutaneous needle or catheter that is taped in place for one or two days. The newer pumps have alarms for battery failure, overdelivery and high pressure in the outflow system. The larger and nonprogrammable early pumps have been largely replaced by smaller, often preprogrammable devices that are easily concealed and do not iterfere with most daily activities. Multiple basal infusion rates can be used for changing activity levels, and meal bolus injections can be adjusted for variable size, quality and timing of meals. These features provide patients with more freedom in their daily lives.

A policy statement from the American Diabetes Association states the primary indication for CSII:

> Failure to achieve an acceptable level of diabetic control in certain type I diabetic subjects with unusual fluctuations in blood glucose levels, despite intensive efforts with proper diet and multiple injections of insulin in single or mixture form and high patient motivation and compliance.

These guidelines include patients who have hyperglycemia associated with elevated glycosylated hemoglobin or patients with frequent hypoglycemic episodes as a result of trying to maintain blood glucose control. Hyperglycemia during pregnancy has been shown to be a definite risk to the fetus, and CSII in this setting can be especially useful for preventing diabetic complications of pregnancy. Some patients with insulin allergies are sensitive to the protamine or zinc in the insulin preparations. These problems can be eliminated or minimized by infusing short-acting crystalline zinc insulin or, if necessary, a zincfree sodium insulin. Diabetic patients without any of the above indications also have used CSII to obtain more freedom in their life-styles—less restriction in meal timing and easier changing of work shifts or travel. Most patients have an improved sense of well-being when using CSII and they prefer to continue to use it even if blood glucose control has not improved. Possibly this is the result of a psychological effect of being in charge of their disease (the internal locus of control).

Data from our University of California, Irvine, clinic shows no statistically significant improvement in hemoglobin A_{1c} levels during 98 patient-years of CSII use in 46 patients. The mean hemoglobin A_{1c} value for these patients, however, was only mildly elevated (8.4%) before pump therapy and was 8.1% during CSII use.

Three major complications of pump therapy are diabetic ketoacidosis, hypoglycemia and infections at the infusion site—all of which have been associated with mortality. Due to the use of short-acting insulin, ketoacidosis develops rapidly when the insulin infusion is interrupted by tubing occlusion, leakage or mechanical failure of the pump. The accumulation of insulin crystals appears to be the main cause of needle occlusions. Ketoacidosis may be severe before blood glucose levels rise significantly, and patients using CSII may present with "euglycemic" ketoacidosis—that is, severe ketonemia preceding the rise in blood glucose concentrations. Various studies have reported a 2 to 17.5 times increase in the rate of ketoacidosis associated with CSII use. In our clinic the ketoacidosis rate is high before CSII use (0.17 events per year) and remained unchanged after CSII use (0.2 events per year). Although less frequent in these patients, hypoglycemia has occurred due to pump "runaway" and inappropriate insulin dosage through patient or provider error. In our clinic, however, the frequency of serious hypoglycemic episodes (requiring a hospital visit), was reduced from 3.0 events per year before to 0.2 events per year during CSII use and 87% of patients reported a greater than 50% reduction or complete elimination of severe hypoglycemic episodes during CSII use. For patients with ineffective glucose counterregulation, we recommend CSII use but alter our lowest acceptable blood glucose concentrations upward to the 100 to 150 mg per dl range. This treatment has produced remarkable results as described above. Insulin preparations contain antibacterial agents, but the indwelling needle or subcutaneous catheter can be a conduit for local infections when left in one site too long.

Among the solutions to these problems are the use of buffered insulins, appropriate insulin dilutions and daily changing of the infusion set and subcutaneous site with antiseptic care during insertion to avoid occlusions and infections. Patients need detailed instructions and repeated rehearsals to insure problem-solving ability. Providers who prescribe CSII use should be aware of the possible complications, and an experienced clinician should be available to patients at all times.

The expense of insulin pumps ($1,000 to $2,500 initial costs plus daily supplies) and the requirement for a high degree of patient knowledge, motivation and participation have limited CSII use. Despite these difficulties, an estimated 8,000 to 10,000 insulin pumps are in use in the United States today. It remains to be proved whether the original goal of preventing long-term diabetic complications in large patient populations through sustained normoglycemia can be realized with CSII any more effectively than with multiple subcutaneous insulin injections combined with self-monitoring of blood glucose levels. We view pump use as an alternative insulin administration method that is associated with some serious complications that must be thoroughly considered before being prescribed and used.

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Human T-Cell Leukemia Virus (HTLV)

A viral cause of malignant conditions in humans has long been suspected, although there has been a paucity of confirmatory evidence. Recently, however, an etiologic association has been made between a unique type C retrovirus called human T-cell leukemia virus (HTLV-I), or adult T-cell leukemia virus (ATLV), and an unusual tumor of mature T cells in humans called adult T-cell leukemia/lymphoma. Originally thought to occur only in geographic areas where the virus is endemic, such as southwestern Japan and the Caribbean, the leukemic process has now been identified in other parts of the world, including the southeastern United States, parts of Africa and South America. This suggests that the virus is more widespread than initially thought. The onset of adult T-cell leukemia/lymphoma may be indolent; recently it has been recognized that clinically well patients may have antibodies to HTLV-I for many years before the development of symptomatic disease. The usual presentation of adult T-cell leukemia/lymphoma is abrupt, however, and is characterized clinically by lymphadenopathy, hepatosplenomegaly, skin lesions that may be clinically and pathologically indistinguishable from those of mycosis fungoides, hypercalcemia, lytic bone lesions and interstitial pulmonary infiltrates due either to lymphomatous infiltrates or to opportunistic infections. Involvement of the central nervous system is not uncommon. Malignant cells are found in the peripheral blood of most patients at some time during their course. Treatment usually consists of combination chemotherapy, though responses are generally short-lived, with few patients surviving more than a year.

The malignant virus-infected cells found in the peripheral blood and tissues of patients with adult T-cell leukemia/lymphoma show a great deal of cytologic variation; typically they are medium-sized pleomorphic lymphocytes with lobulated nuclei. The vast majority possess mature T-cell surface markers characteristic of the helper phenotype (OK T4), although, interestingly, they function as suppressor cells.

HTLV infection is exogenously acquired. The mechanism of its transmission is not yet known, but it appears that sexual contact and prolonged exposure are important. Epidemiologic studies show an increased incidence of antibodies against HTLV-I in clinically normal spouses of patients with adult T-cell leukemia/lymphoma. Transmission of the virus has been accomplished in vitro by cocultivating HTLV-positive T-cell lines with normal cord blood or bone marrow T cells; the newly infected cells acquire the nuclear antigens (p19 and p24), specific reverse transcriptase activity and morphologic characteristics of the HTLV-positive cell lines. Once this RNA virus has infected the host cell, it replicates using its specific reverse transcriptase and integrates its genetic material into host cellular DNA. The virus is T-cell tropic; its proviral sequence is found within DNA of neoplastic T cells but not within nonneoplastic B cells or somatic cells from the same host. The exact mechanism whereby HTLV causes neoplastic transformation is not known, but it does not appear to carry an *onc* gene.

The human T-cell leukemia/lymphoma virus that is associated with adult T-cell leukemia/lymphoma (HTLV-I) belongs to a family of related T-cell tropic viruses. HTLV-II has been isolated from the serum of a patient with hairy cell leukemia. HTLV-III has been identified in blood and saliva of patients with the acquired immunodeficiency syndrome (AIDS) and in patients with the AIDS-related complex, including the lymphadenopathy syndrome. Although Koch's postulates have not been fulfilled, it is currently believed that HTLV-III is the cause of these AIDS-related disorders. The discovery of this unique family of retroviruses has provided an important link in our understanding of the pathogenesis of a variety of T-cell disorders.

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Medicare Freeze Extended Again,

to March 14, 1986

Congress adjourned Friday, December 20, 1985 after being unable to complete the budget reconciliation process.

Before doing so, however, it took emergency action extending current medicare provisions—continuing freeze on fees for non-participating physicians and a freeze on reimbursement for participating physicians until March 14th. It marked the fourth time that medicare and other provisions originally scheduled to have expired at midnight on September 30th have been extended through emergency legislation.

Resumption of the budget reconciliation process is expected to be one of the first items considered by House-Senate conferees when Congress reconvenes on January 21st.

Physicians are to be advised that medicare provisions remain unchanged from what they were before.

Electroconvulsive Therapy

NATIONAL INSTITUTES OF HEALTH

- Electroconvulsive therapy (ECT) is a treatment for severe mental illness in which a brief application of electric stimulus is used to produce a generalized seizure. In the United States in the 1940s and 1950s, the treatment was often administered to the most severely disturbed patients residing in large mental institutions. As often occurs with new therapies, ECT was used for a variety of disorders, frequently in high doses and for long periods. Many of these efforts proved ineffective, and some even harmful. Moreover, its use as a means of managing unruly patients, for whom other treatments were not then available, contributed to the perception of ECT as an abusive instrument of behavioral control for patients in mental institutions for the chronically ill. With the introduction of effective psychopharmacologic medications and the development of judicial and regulatory restrictions, the use of ECT was waned.

The treatment is now used primarily in general hospital psychiatric units and in psychiatric hospitals. A National Institute of Mental Health hospital survey estimated that 33,384 patients admitted to hospital psychiatric services during 1980 were treated with ECT, representing approximately 2.4% of all psychiatric admissions.

Although ECT has been in use for more than 45 years, there is continuing controversy concerning the mental disorders for which ECT is indicated, its efficacy in their treatment, the optimal methods of administration, possible complications, and the extent of its usage in various settings. These issues have contributed to concerns about the potential for misuse and abuse of ECT and to desires to ensure the protection of patients' rights. At the same time, there is concern that the curtailment of ECT use in response to public opinion and regulation may deprive certain patients of a potentially effective treatment.

In recent decades, researchers intensified efforts to establish the effectiveness of ECT and its indications, understand its mechanism of action, clarify the extent of adverse effects, and determine optimum treatment technique. Despite recent research effort yielding substantial information, permitting professional and public evaluation of the safety and efficacy of ECT, the investigation of ECT has not generally been in the mainstream of mental health research.

To help resolve questions surrounding these issues, the National Institutes of Health in conjunction with the National Institutes of Mental Health convened a Consensus Development Conference on Electroconvulsive Therapy from June 10 to 12, 1985. For 1½ days, experts in the field presented their findings, and an audience, including health professionals, former patients, and other interested persons, discussed the issues. A consensus panel representing psychiatry, psychology, neurology, psychopharmacology, epidemiology, law, and the general public considered the scientific evidence and agreed on answers to the following questions:

1. What is the evidence that ECT is effective for patients with specific mental disorders?
2. What are the risks and adverse effects of ECT?
3. What factors should be considered by the physician and patient in determining if and when ECT would be an appropriate treatment?
4. How should ECT be administered to maximize benefits and minimize risks?
5. What are the directions for future research?

1. What Is the Evidence That ECT Is Effective for Patients With Specific Mental Disorders?

Published controlled studies of ECT permit evaluation of its short-term efficacy in severe major depressions

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(delusional and endogenous), in acute mania, and in certain schizophrenic syndromes. The available controlled clinical trials do not extend beyond the treatment of the acute episode (ie, about four weeks). These studies are difficult to compare because they have used differing diagnostic systems and research designs. Further, they have measured outcome only in terms of symptom reduction, not the quality of life and social functioning.

Depression—Studies of ECT in depression have used various control conditions for comparison, including "sham" ECT (eg, all of the elements of the ECT procedure except the electric stimulus), tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs), combinations of antidepressants and neuroleptics, and placebos. The efficacy of ECT has been established most convincingly in the treatment of delusional and severe endogenous depressions, which make up a clinically important minority of depressive disorders. Some studies find ECT to be of at least equal efficacy to medication treatments, and others find ECT to be superior to medication. Not a single controlled study has shown another form of treatment to be superior to ECT in the short-term management of severe depressions. It must be noted, however, that those studies that found ECT to be superior to medication were not designed to study the persistence of this advantage of ECT beyond the short term. Moreover, the available evidence suggests that relapse rates in the year following ECT are likely to be high unless maintenance antidepressant medications are subsequently prescribed. Several studies suggest that ECT reduces symptoms in severely depressed patients who previously have not responded to adequate trials of antidepressant medication. The literature also indicates that ECT, when compared with antidepressants, has a more rapid onset of action.

Delusional Depression—Electroconvulsive therapy is highly effective in the treatment of delusional depression. It is superior to either antidepressants or neuroleptics used alone and is at least as effective as the combination of antidepressants and neuroleptics. It is often effective in patients who have previously failed to respond to medication. The duration of therapeutic effect beyond the initial acute episode is not clear.

Endogenous/Melancholic Depression—The severe endogenous/melancholic depressions are characterized by early morning awakening, marked weight loss, psychomotor retardation and/or agitation, diurnal variation, and lack of reactivity. Electroconvulsive therapy is at least as effective as tricyclic antidepressants and more effective than sham ECT in the short-term treatment of these severe endogenous/melancholic depressions. It appears to be more effective than MAOIs in the treatment of severe depressions, but available studies have generally used relatively low MAOI doses. There is evidence for the efficacy of ECT in those persons with endogenous depressions who have not responded to an adequate trial of antidepressants. The long-term efficacy of ECT with endogenously depressed patients is not known.

Other Depression—The majority of depressed persons encountered in medical and psychiatric settings do not have the severe endogenous/melancholic or delusional depressions described above. Electroconvulsive therapy is not effective for patients with milder depressions, ie, dysthymic disorder (neurotic depression) and adjustment disorder with depressed mood. Patients with major depression that is nonendogenous/nonmelancholic have not yet been extensively studied. Because of this, it is unclear whether their response to ECT would be more like those with dysthymic disorders or those with endogenous/melancholic features.

Acute Manic Episode—Electroconvulsive therapy and lithium appear to be equally effective for acute mania, and either is superior to hospitalization without somatic therapy. A treatment regimen in which ECT is used for the acute episode, followed by lithium maintenance, does not appear to be associated with an increased risk of early relapse compared with lithium treatment alone.

Schizophrenia—Neuroleptics are the first line of treatment for schizophrenia. The evidence for the efficacy of ECT in schizophrenia is not compelling but is strongest for those schizophrenic patients with a shorter duration of illness, a more acute onset, and more intense affective symptoms. It has not been useful in chronically ill schizophrenic patients. Although ECT is frequently advocated for treatment of patients with schizophreniform psychoses, schizoaffective disorders, and catatonia, there are no adequate controlled studies to document its usefulness for these disorders.

Other Disorders—There are no controlled studies supporting the efficacy of ECT for any conditions other than those designated above (ie, delusional and severe endogenous depression, acute mania, and certain schizophrenic syndromes).

2. What Are the Risks and Adverse Effects of ECT?

To maximize the benefits of ECT and minimize the risks, it is essential that the patient's illness be correctly diagnosed, that ECT be administered only for appropriate indications, and that the risks and adverse effects be weighed against the risks of alternative treatments. Risks and adverse effects of ECT can be divided into two categories: (1) those medical complications that can be substantially reduced by the use of appropriately trained staff, best equipment, and best methods of administration and (2) those side effects, such as spotty but persistent memory loss and transient posttreatment confusion, that can be expected even when an optimal treatment approach is used. In this report, we will focus on the risks still present with adequate treatment techniques.

In the early days of ECT, mortality was a significant problem. The commonly quoted overall mortality rate in the first few decades was 0.1%, or one per 1,000. Over the years, safer methods of administration have been developed, including the use of short-acting anesthetics, muscle relaxants, and adequate oxygenation. Present mortality is very low. In the least favorable recent series reported, there were 2.9 deaths per 10,000 patients. In another series, 4.5 deaths per 100,000 treatments were reported. Overall, the risk is not different from that associated with the use of short-acting barbiturate anesthetics. The risk of death from anesthesia, although very small, is present and should be considered when evaluating the setting for performing ECT.

In the past, up to 40% of patients suffered from various complications, the most common being vertebral compression fractures. With present techniques, these risks have been virtually eliminated. In one recent study of almost 25,000 treatments, a complication rate of one per 1,300 to 1,400 treatments was found. These included laryngospasm, circulatory insufficiency, tooth damage, vertebral compression fractures, status epilepticus, peripheral nerve palsy, skin burns, and prolonged apnea.

During the few minutes following the stimulus, profound and potentially dangerous systemic changes occur. First, there may be transient hypotension from bradycardia caused by central vagal stimulation. This may be followed by sinus tachycardia and also sysmpathetic hyperactivity that leads to a rise in blood pressure, a response that may be more severe in patients with essential hypertension. Intracranial pressure increases during the seizure. Additionally, cardiac arrhythmias during this time are not uncommon (but usually subside without sequelae). Thus, certain patient groups that would be adversely affected by these manifestations are at increased risk.

There are two categories of central nervous system effects: the immediate consequences of the ECT seizure and the more enduring effects, both of which are affected by the treatment course. Immediately after awakening from the treatment, the patient experiences confusion, transient memory loss, and headache. The time it takes to recover clear consciousness, which may be from minutes to several hours, varies depending on individual differences in response, the type of ECT administered, the spacing and number of treatments given, and the age of the patient.

The severity of this acute confusional state is greatest after bilateral sine wave treatment and least when nondominant unilateral pulsed ECT is administered. Severity also appears to be increased by longer seizure duration, close spacing of the treatments, increasing dosage of electrical stimulation, and each additional treatment.

Depressive disorders are characterized by cognitive deficits that may be difficult to differentiate from those caused by ECT. It is, however, well established that ECT produces memory deficits. Deficits in memory function, which have been demonstrated objectively and repeatedly, persist after the termination of a normal course of ECT. Severity of the deficit is related to the number of treatments, type of electrode placement, and nature of the electric stimulus. Greater deficit occurs from bilateral than from unilateral placement. Since wave current has been found to impair memory more than pulsed current.

The ability to learn and retain new information is adversely affected for a time following the administration of ECT; several weeks after its termination, however, this ability typically returns to normal. There is also objective evidence based on neuropsychological testing, of loss of memory for a few weeks surrounding the treatment; such objective tests have not firmly established persistent or permanent deficits for a more extensive period, particularly for unilateral ECT. However, research conducted as long as three years after treatment has found that many patients report that their memory was not as good as it was prior to the treatment. They report particular difficulties for events that occurred on average six months before ECT (retrograde amnesia) and on average two months after the treatment (anterograde amnesia). Because there is also a wide difference in individual perception of the memory deficit, the subjective loss can be extremely distressing to some and of little concern to others.

There are other possible adverse effects from ECT. Some patients perceive ECT as a terrifying experience, some regard it as an abusive invasion of personal autonomy, some experience a sense of shame because of the social stigma they associate with ECT, and some report extreme distress from persistent memory deficits. The panel heard eloquent testimony of these attitudes from former patients who had been treated with ECT. It is clear, however, that these attitudes are not shared by all ECT patients. The panel also heard moving testimony from former patients who regarded ECT as a wholly beneficial and lifesaving experience. There are insufficient systematic studies to permit any definitive assessment of the prevalence of these various perceptions among ECT patients.

Numerous ECT studies have been conducted with animal models. Many of these suffer from methodological shortcomings. In studies that have been controlled for fixation artifacts, hypoxia, and other methodological problems, neuronal cell death has not been detected. Cerebral vasospasm and alterations in capillary permeability are of short duration and of insufficient magnitude to lead to neuronal cell death. The precise mechanism of the anterograde and retrograde memory deficit has not been established; it may represent alterations in neuronal function that are not detectable with present methods. Computed tomography studies of patients who have had ECT are very preliminary and open to alternative interpretations. Definitive studies of in vivo brain metabolism with positron emission tomography and studies of tissue changes detectable by magnetic resonance imaging remain to be done.

3. What Factors Should Be Considered by the Physician and Patient in Determining If and When ECT Would Be an Appropriate Treatment?

The consideration of ECT is most appropriate in those conditions for which efficacy has been established: delusional and severe endogenous depressions, acute mania, and certain schizophrenic syndromes. It should rarely be considered for other psychiatric conditions. The decision to offer ECT to an individual patient should be based on a complex consideration of advantages and disadvantages for ECT and for each treatment alternative. Whether to use ECT should be based on a thorough review of severity of the patient's illness, medical indications and contraindications, and nonresponsiveness to other treatments. It should be emphasized that for certain patients with very specific and narrow indications, ECT may be the only effective treatment available. In certain circumstances of acute risk to life or of medical status incompatible with the use of other effective treatments, ECT may be the first treatment.

The panel is concerned that ECT only be administered for the benefit of individual patients. Institutional factors (such as financial pressures created by prospective systems or staff convenience) should play no role in the decision to administer ECT.

Severity—Given a diagnosis for which the efficacy of ECT has been established, the immediate risk of suicide (when not manageable by other means) is a clear indication for the consideration of ECT. Acute manic episodes—especially when characterized by clouded sensorium, dehydration, extreme psychomotor agitation, high risk for serious medical complications or death through exhaustion, and nonresponse to pharmacological interventions—are also clear indications for ECT. The severe and unremitting nature of the patient's emotional suffering, or extreme incapacitation, are also important considerations.

Medical Indications and Contraindications—The patient's medical status is often the determining consideration in the use of ECT. Electroconvulsive therapy may be necessary when the patient has medical conditions that preclude the use of tricyclic antidepressants, MAOIs, lithium, and neuroleptics. It should be considered in patients with severe depression or psychosis during the first trimester of pregnancy. Conversely, ECT is contraindicated for increased intracranial pressure, while space-occupying lesions in the brain, a recent history of myocardial infarction, and large aneurysms are relative contraindications for ECT. A personal history of nonresponsiveness to or debilitating side effects (medical or psychological) from ECT are also possible contraindications.

Nonresponsiveness to Other Treatments—Electroconvulsive therapy should be considered when alternative pharmacological and/or psychotherapeutic treatments have been given an adequate trial without efficacious response. When a patient is nonresponsive to other treatments, factors such as severity of the illness, its natural course, and the risk of other treatments worsening the course (as, for example, antidepressant medications precipitating a manic episode) need to be taken into account.

Informed Consent—When the physician has determined that clinical indications justify the administration of ECT, the law requires, and medical ethics demand, that the patient's freedom to accept or refuse the treatment be fully honored. An ongoing consultative process should take place. In this process, the physician must make clear to the patient the nature of the options available and the fact that the patient is entitled to choose among those options.

No uniform "shopping list" can be drawn up regarding the matters that should be discussed by patient and physician to ensure a fully informed consent. They should discuss the character of the procedure, its possible risks and benefits (including full acknowledgment of post-treatment confusion, memory dysfunction, and other attendant uncertainties), and the alternative treatment options (including the option of no treatment at all). Special individual needs may also be relevant to some patients, for example, a personal situation that requires rapid remission to facilitate return to work and to reduce family disruption. In all matters, the patient should not be inundated with technical detail; the technical issues should be translated into terms meaningful and accessible to the patient.

It is not easy to achieve this ideal of "informed consent" in any aspect of medical practice, and there are special difficulties that arise regarding the administration of ECT. In particular, the patients for whom this procedure is medically appropriate may be suffering from a severe psychiatric illness that, although not impairing their legal competency to consent, may nonetheless cloud judgment in fully weighing all of the available options. Such judgmental distortion does not justify disregarding the patient's choices; rather, it makes it all the more important that the physician strive to identify and clarify the options that the patient alone is entitled to exercise.

The consent given by the patient at the outset of treatment should not be the final exchange on this issue but should be reexamined with the patient repeatedly throughout the course of treatment. These periodic reviews should be initiated by the physician and not depend on patient initiative to "rescind" consent.

There are several reasons for this repeated consenting procedure: because of the relatively rapid therapeutic effect of the procedure itself, the patient after initial treatments is likely to have enhanced judgmental capacities; the risks of adverse effects increase with repeated treatments, so that the question of continued treatment presents a possibly changed risk/benefit assessment for the patient; and because of the short-term memory deficits that accompany each administration of ECT, the patient's recollection of the prior consenting transaction might itself be impaired, so that repeated consultations reiterating the patient's treatment options are important to protect the patient's sense of autonomy throughout the treatment process. Moreover, if the patient agrees, the family should be involved in each step of this consultative process.

In a small minority of cases, a patient will lack adequate legal capacity to consent to the proposed procedure. In such cases, timely court proceedings are necessary if treatment is to be provided. Legislation in a few states dictates that ECT may in no circumstance be provided to an involuntarily committed patient. The panel believes that such absolute bans are unduly restrictive and make treatment impossible for patients who might obtain more benefit, at acceptable levels of risk, from ECT than from alternative treatments.

It may be desirable for physicians with patients for whom the prospect of ECT is a foreseeable but not immediate possibility to discuss this in advance with the patient when his or her judgment appears least compromised by the underlying disease process. Such advance discussion would serve as a nonbinding guide both to the patient and physician and would be another means to enhance the patient's autonomous choice in weighing the risks and benefits of this procedure and its alternatives.

4. How Should ECT Be Administered to Maximize Benefits and Minimize Risks?

Once the patient and the physician have decided that ECT may be indicated, the patient should undergo a pretreatment medical examination that includes a history, physical and neurological examination, electrocardiogram, and laboratory tests. Medications that affect the seizure threshold should be noted, and their use should be decreased or discontinued when clinically feasible. Use of MAOIs should be discontinued two weeks before treatment, and patients should be essentially lithium free. Severe hypertension should be controlled before beginning treatment. Because some patients with compromised cardiovascular status will be receiving ECT, cardiac conditions should be evaluated and monitored closely. Educating the patient and the family through discussion and written and/or audiovisual material describing the procedure is necessary prior to obtaining written informed consent.

An area should be designated for the administration of ECT and for supervised medical recovery from the treatment. This area should have appropriate health care professionals available and should include equipment and medications that could be used in the event of cardiopulmonary or other complications from the procedure.

A health professional specifically trained and certified in the use of brief anesthetic procedures should administer the anesthesia. The treatment team should include nursing personnel trained in ECT procedures and recovery.

Typically, ECT is administered as follows: The treatment is given in the early morning after an eight- to 12-hour period of fasting. Atropine or another anticholinergic agent is given prior to the treatment. An intravenous line is placed in a peripheral vein, and access to this vein is maintained until the patient is fully recovered. The anesthetic methohexital is given first, followed by succinylcholine for muscle relaxation. Ventilatory assistance is provided with a positive-pressure bag using 100% oxygen. The electrocardiogram, blood pressure, and pulse rate should be monitored throughout the procedure. Stimulus electrodes are placed either bifrontemporally (bilateral) or with one electrode placed frontotemporally and the second electrode placed on the ipsilateral side (unilateral). Bilateral ECT may be more effective in certain patients or conditions. It has been established, however, that unilateral ECT, particularly on the nondominant side, is associated with a shorter confusional period and fewer memory deficits. Also, a brief pulse stimulus is associated with fewer cognitive defects than the traditional sine wave stimulus. Seizure threshold varies greatly among patients and may be difficult to determine; nevertheless, the lowest amount of electrical energy to induce an adequate seizure should be used. Seizure monitoring is necessary and may be accomplished by an electroencephalogram or by the "cuff" technique. In the cuff technique, a blood pressure cuff is placed on the arm or leg and is inflated above systolic pressure prior to the injection of a muscle-relaxing agent. In unilateral ECT, the cuff should be on the same side as the electrodes to ensure that a bilateral seizure occurred.

The number of treatments in a course of therapy varies. Six to 12 treatments are usually effective. In the United States, the usual frequency is three times weekly; in the United Kingdom, the standard practice is two treatments weekly. Regressive ECT (a large number of treatments given within a short period for the purpose of achieving a persistent organic brain syndrome) is no longer an acceptable treatment form. Multiple-monitored ECT (several seizures during a single treatment session) has not been demonstrated to be sufficently effective to be recommended. There are no controlled studies on the periodic use of ECT after remission of the acute episode or as a maintenance regimen to prevent recurrence of new episodes. Following ECT, most depressed patients should continue using antidepressant medication or lithium to reduce relapse.

The panel is concerned that there are only limited data on the manner and extent of ECT administration in the United States and on the training of personnel involved in it. A national survey should be undertaken to assemble basic facts about the status of ECT treatment.

Medical school curricula should include education in the use of ECT. Psychiatric residency programs should include complete ECT training: indications, contraindications, risks, clinical management, informed consent, and evaluation of outcome. The American Board of Psychiatry and Neurology should include questions about ECT in its oral and written examinations.

The panel believes it is imperative that appropriate mechanisms be established to ensure proper standards and monitoring of ECT. Hospitals and centers using ECT should establish review committees modeled on other medicosurgical review committees and should formulate rules and regulations to govern the privileging of physicians giving the treatments. Stringent peer review consistent with Joint Commission for the Accreditation of Hospitals standards should monitor ongoing utilization of ECT. Periodic inspection of the equipment is also essential. As experience accumulates, consideration should be given to the adequacy of existing monitoring and review mechanisms.

5. What Are the Directions for Future Research?

Electroconvulsive therapy has been underinvestigated in the past. Among the most important immediate research tasks are the following:

- Initiation of a national survey to assemble the basic facts about the manner and extent of ECT use, as well as studies of patient attitudes and responses to ECT. Better understanding of negative, positive, and indifferent responses should result in improved treatment practices.
- Identification of the biologic mechanisms underlying the therapeutic effects of ECT and the memory deficits resulting from the treatment.

- Identification of the biologic mechanisms underlying the therapeutic effects of ECT and the memory deficits resulting from the treatment.

- Better delineation of the long-term effects of ECT on the course of affective illnesses and cognitive functions, including clarification of the duration of ECT's therapeutic effectiveness.
- Precise determination of the mode of electrode placement (unilateral vs bilateral) and the stimulus parameters (form and intensity) that maximize efficacy and minimize cognitive impairment.
- Identification of patient subgroups or types for whom ECT is particularly beneficial or toxic.

Conclusion

Electroconvulsive therapy is the most controversial treatment in psychiatry. The nature of the treatment itself, its history of abuse, unfavorable media presentations, compelling testimony of former patients, special attention by the legal system, uneven distribution of ECT use among practitioners and facilities, and uneven access by patients all contribute to the controversial context in which the consensus panel has approached its task.

The panel has found that ECT is demonstrably effective for a narrow range of severe psychiatric disorders in a limited number of diagnostic categories: delusional and severe endogenous depression and manic and certain schizophrenic syndromes. There are, however, significant side effects, especially acute confusional states and persistent memory deficits for events during the months surrounding the ECT treatment. Proper administration of ECT can reduce potential side effects while still providing for adequate therapeutic effects.

The physician's decision to offer ECT to a patient and the patient's decision to accept it should be based on a complex consideration of advantages and disadvantages of ECT compared with alternative treatments. An ongoing consultative process, requiring time and energy on the part of both patient and physician, should occur.

Much additional research is needed into the basic mechanisms by which ECT exerts its therapeutic effects. Studies are also needed to identify better the subgroups for whom the treatment is particularly beneficial or toxic and to refine techniques to maximize efficacy and minimize side effects. A national survey should be conducted on the manner and extent of ECT use in the United States.

These recommendations reflect the consensus of the panel. We have been careful to narrowly delineate when and how, in our judgment, ECT should be administered. To prevent misapplication and abuse, it is essential that appropriate mechanisms be established to ensure proper standards and monitoring of ECT.

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Obstetrical Malpractice or How Not to Get Sued

HARVEY F. WACHSMAN, M.D., J.D.

Great advances have been made by dedicated physicians in the field of obstetrical and fetal medicine making it possible to sharply reduce the incidence of maternal and newborn mortality and morbidity. Progress and advances carry attendant responsibility. The death of or serious injury to a young mother or newborn infant are among the most tragic occurrences existing in our society. As such, enormous responsibility to reduce or minimize tragic consequences lies with personnel who must render quality obstetrical and fetal medical care.

The goal in perinatal medicine should be the diminution in infant morbidity and mortality rates, in which injuries were as a consequence of an "antagonistic antepartum, intrapartum or postpartum course."

How vulnerable is the obstetrician? What should the obstetrician do?

I. From a financial point of view, of course, the obstetrician is vulnerable only if he or she does not have adequate malpractice liability insurance coverage. The enormous financial and emotional impact incurred as a result of a perinatally brain damaged baby greatly increases any award. Therefore, purely from a financial point of view, the prudent obstetrician must do the following:

(a) Obtain the maximum primary insurance coverage.

(b) Determine if awards in his or her state may exceed that primary insurance coverage, and if so, obtain excess coverage.

(c) Make certain that the type of insurance policy will protect the obstetrician should any claim arise in the future. For example, a birth in one year may give rise to a claim many years later. With an "Occurrence Policy," the obstetrician will be covered whenever the claim is filed. With a "Claims Made" policy, the obstetrician will not be covered unless there is an additional policy purchased known as a "tail." The obstetrician must be aware of the difference and make certain that he or she is covered.

II. What are the personal and professional vulnerabilities of the obstetrician? What should the obstetrician do to avoid personal and professional vulnerability?

Apart from any financial aspects, the obstetrician should be aware of what his or her personal and professional vulnerability may be. Even if the obstetrician is financially secure through adequate insurance coverage, there still remains the issue of personal and professional responsibility and vulnerability.

What should the obstetrician do to avoid liability?

At the risk of being oversimplistic, the obvious answer is to practice good obstetrics. Yet, some obstetricians may respond that they know of colleagues who have practiced good obstetrics and nevertheless been sued. We live in a society in which the Courthouse doors are open. There is nothing the obstetrician can do to prevent an unjustifiable suit. To defend such a suit, comfortable in one's ability to explain and justify the medical management is one circumstance. However, when medical management cannot be explained or justified, then a position of professional and personal vulnerability is assumed.

The next portion of this paper addresses examples in which medical management is questioned.

1. *Abruptio placentae.*

One case came to us recently, in which the baby was severely brain damaged due to the hypoxic effects of separated placenta. The mother advised us that she awoke in the middle of the night with vaginal bleeding, and called her obstetrician. She states she was rushed by the rescue unit to the hospital, but maintains that she waited for the obstetrician to arrive. Eventually, an emergency Cesarean Section was performed. The hospital record, however, reflects that the attending obstetrician arrived just a few minutes after the mother was admitted, and that within twenty minutes of the obstetrician's arrival, the baby was delivered with a low Apgar and in respiratory distress. A pediatrician who had been summoned arrived within minutes and resuscitative efforts were timely, coordinated and effec-

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tive. Within hours, the baby was stabilized and transferred to a neonatal intensive care unit at another hospital. Police records and rescue squad records confirmed the hospital time of admission, and disputed the mother's recollection that she was waiting for the obstetrician. This case was not accepted by our office.

An attorney might pursue this case on the theory that the Cesarean Section should have been performed sooner. If such a case were pursued, the obstetrician could be comfortable in the defense that he immediately came to the hospital, and performed an emergency Cesarean Section with due speed, bearing in mind the safety of both mother and baby.

Compare the facts of this latter case with one that our office is pursuing. The mother complaining of vaginal bleeding was seen by the attending obstetrician in his office at 5:00 p.m. An internal examination was performed and the obstetrician concluded that the condition was nonpathologic, and advised the patient to return home. At 2:00 a.m. the following day, the patient experienced heavy vaginal bleeding and called the obstetrician's answering service. The obstetrician responded and advised the patient to go to the hospital. The patient arrived at the hospital within a half hour, but the attending obstetrician was not present. Instead, the attending obstetrician had requested the house staff to evaluate the patient. The hospital record confirms that the patient was at the hospital for over one hour before an external fetal monitor was applied. The attending obstetrician was notified of abnormal tracings, but did not arrive until one-half hour later. One hour and fifteen minutes thereafter, an emergency Cesarean Section was accomplished, resulting in the delivery of a severely depressed, ultimately brain damaged baby due to a placental separation. An abruptio placentae is, of course, an obstetrical emergency requiring early recognition and prompt delivery. The failure to timely admit the patient to the hospital; the failure to timely evaluate the patient once she was in the hospital; the failure to prepare for an emergency Cesarean Section; an inexplicable delay even after recognition of the need for an emergency Section, form the basis for what we believe to be a valid case. The latter circumstances lead the attending obstetrician to have personal and professional vulnerability. It will be incumbent upon him to explain just why he was not there observing his patient, when he knew, or should have known, that a current or potential emergency situation existed. This coupled with the laxity on the part of the house staff and failure to coordinate the activities of the house staff and attending, in our view make both the hospital and the obstetrician vulnerable.

The latter case represents in my view, a truly avoidable perinatal catastrophe which I believe will be successful. The pregnancy was 37 weeks and there was the potential danger that the patient might go into labor at home with a placental complication. The safer practice would have been to admit the patient to the hospital and carefully evaluate and observe. The obstetrician will have to explain why he did not elect the safer alternative of hospitalization.

Once the patient called complaining of heavy vaginal bleeding the obstetrician elected not to meet her at the hospital but rather to await a call from the house staff in case it was just a "false alarm." The obstetrician will have to explain why he elected to wait rather than choose the safer alternative of meeting his patient at the hospital.

Once the patient was at the hospital, the burden of explaining the delay of one hour before a monitor was applied will be upon hospital personnel and the attending obstetrician. Someone will have to explain why an hour went by before this patient had any fetal heart rate monitoring.

Once fetal monitoring was begun, a diagnosis of fetal distress was made. It was not for another one hour and 45 minutes before the baby was delivered by emergency Cesarean Section. Once again the attending obstetrician and the house staff will have to explain the delay.

Careful prenatal management and evaluation; use of sonography and stress and non-stress tests; electronic fetal monitoring; and the ability to execute an indicated emergency Cesarean Section are all integral parts of modern perinatal medicine designed and intended to avoid the very result which occurred.

2. *Electronic Fetal Monitor.*

One case that we recently evaluated involved a woman in labor with an external electronic fetal monitor in place, achieving adequate tracings. A dip in the fetal heart rate below 100 was immediately recognized by the labor room nurse, and the attending obstetrician was at the patient's bedside within minutes thereafter. The patient was turned on her left side, oxygen was administered, and an internal monitor applied. The attending obstetrician remained at the patient's bedside noting that the fluid remained clear and the internal tracings produced recordings within a normal range. An hour and a half later, the baby was delivered vaginally, in apparent good condition, and the child's neonatal course was "stable." Ultimately, this child was diagnosed as being brain damaged, but the cause was never clearly established. This case was rejected by our office, on the basis that the single deceleration determined by external monitor was not sufficient basis to do an emergency Cesarean Section; the attending obstetrician was present and employed appropriate care by evaluating the patient's fluid, and inserting an internal monitor; and thereafter, supported by normal and stable tracings, the attending obstetrician correctly used his judgment to allow the labor to continue.

This latter case may be compared with another that we are now pursuing involving a mother who was admitted to the hospital in early labor. The admitting examination reveals a documented fetal heart rate of 114. While this relatively low heart beat in and of itself was not cause for immediate action, it certainly was a "red flag." Shortly thereafter, the membranes were ruptured revealing clear fluid and an external monitor was applied. For the next 3½ hours, the tracings of the external monitor could at best be described as artefacts, and many of the tracings were highly suggestive of severe declerations and loss of beat to beat variability. The record does not demonstrate the presence of the attending obstetrician during this 3½ hours, or any comment about the amniotic fluid, which at the time of birth was noted to be meconium stained. At the end of this 3½ hour interval, an internal monitor was inserted, demonstrating a baseline of 170-180 beats per minute with Type II decelerations down to 60 beats per minute. The mother was 7 cm dilated. The attending obstetrician was summoned, whereupon, he ordered pitocin, presumably to hasten the delivery. Pitocin infused for 15 minutes producing hypertonic contractions and a worsening of the already serious fetal heart rate pattern. The pitocin was thereupon discontinued and an emergency section performed.

This case was accepted on the basis that this child has brain damage consistent with hypoxia, and that there was an inappropriate delay in recognizing fetal distress. The theory of liability would be based on the contention that the external monitor should have been properly positioned to obtain appropriate tracings. Assuming for some reason the external monitor could not obtain appropriate tracings, then it was indicated to immediately employ an internal monitor—particularly in view of the relatively low fetal heart beat on admission. An internal monitor could have detected early signs of fetal distress which might then have been confirmed in a timely fashion through the observation of the amniotic fluid and determination of a scalp pH. The fetal distress appeared to be contraction related. Therefore, it was inappropriate to exacerbate the situation through the use of pitocin. It is our view that the attending obstetrician, as well as the hospital house staff will not be able to justify the 3½ hours of external fetal monitor tracings or the use of pitocin.

3. *Forcep deliveries.*

We have evaluated a number of cases in which elective prophylactic low forceps have been employed. Many of these cases have been found to have no merit as the atraumatic elective use of such forceps was indicated and caused the baby no harm.

We are currently pursuing two cases that involve traumatic forcep deliveries which are of interest.

One case involves a service patient who received her prenatal care at the local health clinic. The only significant prenatal comment was that this primip had a "borderline" pelvis. The mother was admitted to the hospital in labor and was followed initially by a first-year house officer, who was unfamiliar with interpreting external fetal monitor tracings. The tracings suggest at least an hour and a half of fetal distress when the attending on service, "looked in on the patient." The attending had no prior contact with this patient, and having practiced since the late 1940s was not very familiar with electronic fetal heart rate monitoring. He did not recognize evidence of fetal distress.

The obstetrician decided to wait another hour to see if there would be progress. One hour later and still no progress at station + 1, the obstetrician attempted a rotation from a posterior to an anterior position. Rotation was unsuccessful to the right, so he tried rotating to the left by raising the head up. Unfortunately, he raised the head so high that he obtained a proplapse of the cord. The obstetrician then rotated back to the posterior position. He then applied a new set of forceps, bringing the baby down to the perineum and then rotated once again, with the result that the baby was severely depressed with a fractured skull. The obstetrician defended his delivery by claiming that he had been doing this type of forcep delivery for some thirty-five years and that he did not agree that Cesarean Section was preferable to traumatic forcep delivery.

The second case of interest involved a foreign-trained obstetrician who came on staff of a small hospital, having only one other obstetrician. Neither was Board Certified. Our client was a primip, fully dilated in labor for approximately 10 hours with the baby at station 0. The obstetrician decided to do an elective mid-forcep rotation while the nurse was applying fundal pressure. The result was a "failed forcep," and ultimately an emergency Cesarean Section, producing a brain-damaged baby.

I raise several suggestions which, if complied with, might prove successful in reducing perinatal morbidity and mortality:

1. If you are to practice obstetrics, make certain that you are adequately trained. In my view the day of the general practitioner dabbling in obstetrics has hopefully become passé.
2. The hospital obstetrical unit must be staffed by trained personnel. At the very least a Board Certified Obstetrician should be in charge of the Department. Nursing and house staff coverage must be sufficiently trained for adequate surveillance of labor.
3. The attending obstetrician must keep abreast of new developments. Amniocentesis, sonography, non-stress tests, and stress tests, etc. These procedures, when indicated, coupled with careful prenatal care, must be employed to detect high risk pregnancies. A patient must not be made to fit into the doctor's routine. Use of these tests with toxemia; possibility of twins; possible post-datism, C.P.D., etc., must be employed. An obstetrician must err on the side of caution rather than assume that all will be well.
4. When confronted with a circumstance that may be an

emergency the obstetrician must assume that an obstetrical emergency exists until proven otherwise. Once again the obstetrician must err on the side of caution.

5. The obstetrician must be in attendance when the patient is in active labor. The obstetrician should not rely on the nurse or an inexperienced resident. Modern perinatal intrapartum care is geared toward early detection of fetal distress and prevention of perinatal morbidity by timely Cesarean Section when indicated. The obstetrician must be in attendance for the system to work.
6. The electronic fetal monitor has now become so accepted in modern perinatal medicine that it seems to be foolhardy not to have one and use it. The external monitor will not function properly unless it is appropriately positioned and if necessary repositioned. This requires at the very least constant nursing supervision. When indicated, an internal monitor should be applied and when there are questions of the existence or absence of fetal distress, a scalp pH should be employed.
7. Traumatic forcep and breech deliveries have hopefully become history. The trained obstetrician should be sufficiently skilled so that traumatic deliveries may be avoided.
8. Use of oxytocin agents to induce or stimulate labor for the convenience of physician or patient is hopefully no longer considered acceptable. An obstetrician should give as much thought into determining whether to use oxytocin as in determining whether to use forceps. If there is a proper indication, then of course it may be used – but only with proper care and surveillance while in use.
9. Excessive analgesics and anesthesia for maternal comfort can, of course, adversely affect the newborn. Avoidance of a narcotized baby is, of course, important. However, if the baby is depressed, whether from intrauterine hypoxia and/or medications, the recognition and treatment is crucial. Even if the obstetrician is not personally administering to the newborn, it is imperative that the obstetrician make certain that adequate personnel is present to deal with respiratory complications.
10. Honesty is essential. Obstetricians must be forthright with their patients, other physicians, nurses. The medical records must reflect the truth.
11. When neonatal complications are anticipated, referral to an institution with a neonatal intensive care unit is required.

Conclusion

Standards of care of perinatal medicine exist in a constant state of flux changing as progress is made. It is essential that the obstetrician keep abreast of the standards of care and comply. The latter statement is easy to make, but requires great effort. However, if strictly adhered to, will lead to a significant reduction in birth related injury, as well as obstetrical vulnerability.

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Physician Mortality and Suicide

Results and Implications of the AMA-APA Pilot Study

AMA COUNCIL ON SCIENTIFIC AFFAIRS

Introduction

Responding to resolutions 49 and 50 (I-79) and 75 (I-80) on physician suicide and physician mortality, the Board of Trustees (Report V, A-80; Report V, I-80; Report G, A-81) authorized a pilot project in cooperation with the American Psychiatric Association (APA) to examine the causes of physician deaths in five states.*

The purposes of the project were:

1. To study in depth physician and medical student suicide in order to enhance its prevention through
   a. improved detection, diagnosis and treatment of physicians who may be in danger of dying prematurely from self-inflicted causes.
   b. improved training of physicians.
2. To determine current causes of physician mortality in general and to compare the results with earlier studies of physicians and other groups.

Arizona, California, Michigan, Oregon and Pennsylvania, comprising approximately 24% of the U.S. physician population, were selected for the study. Managers were appointed for each of the pilot states through the APA and its Impaired Physicians Committee to direct the interviewing of next-of-kin and other survivors and associates of the deceased.

From the AMA's Physician Records Section all death reports posted from these states in 1980 and 1981 were examined. Confirmed suicides were identified, as were possible suicides, i.e., those deaths that met one or more of the following criteria: (1) any death under age 40 not readily attributable to organic disease, (2) any death caused by gunshot wounds or hunting accident, (3) any death in a single car accident, (4) death under ambiguous circumstances, such as carbon monoxide poisoning or single occupant plane crashes, (5) any death where cause was not known.

A random sample of other deaths from the pilot states constituted a control group for interviewing purposes.

A total of 1,258 deaths were posted for the pilot states for the two year period. Of these 24 were listed as suicides, 128 identified as possible suicides and the remaining 1,106 listed as deaths from other causes.

Selected for personal follow-up were 223 deaths. They included all of the suicides and possible suicides, as well as a random sample of 71 of the deaths from other causes that were posted in 1980 and the first half of 1981. The last cohort constituted a control group for interviewing purposes. After receiving details from the death reports, prospective interviewers recruited by managers and district branches of the APA attempted to arrange for visits with surviving spouses or other appropriate persons.

Breakdown of Deaths Selected for Interview-Follow-Ups

Interviews were successfully completed on 61, or 27%, of the deaths selected for follow-up. Most of the unsuccessful attempts were due to inability to locate next-of-kin or other survivors, rather than to reluctance of widows or others to be interviewed.

Table 1 gives a state-by-state breakdown of the deaths selected in the three categories of suicides, possible suicides, and others. Table 2 shows the number in each of these categories that were represented in the interviews that actually took place. As a result of the interviews, six of the possible suicides were reclassified as definite suicides, six remained as questionable suicides, and the rest were designated as deaths from other causes.

(*A Panel on Physician Mortality was appointed by the Council on Scientific Affairs to advise on the project's operation, to coordinate with the APA's Impaired Physicians Committee, to assess findings and to propose recommendations. This report reflects the considered judgment of the Panel under the chairmanship of Douglas A. Sargent, M.D., Grosse Point Farms, MI. Panel members were LeClair Bissell, M.D., NY; Ralph Crawshaw, M.D., Portland, OR; Donald M. Keith, M.D., Seattle; Edward A. Seidel, M.D., Oakland, CA; and J. Patrick Tokarz, M.D., Alexandria, VA. Robert E. Jones, M.D., Philadelphia, Chairman of APA's Impaired Physician Committee, participated in all of the Panel's meetings, and Rogers J. Smith, M.D., Portland, OR, served as liaison to the Panel from the Council on Scientific Affairs.)

Action of the House of Delegates. Report G of the Council on Scientific Affairs *adopted.*

Table 1

DISTRIBUTION, BY LISTED CAUSE, OF DEATH REPORTS SELECTED FOR PERSONAL FOLLOW-UP

	Suicides	*Possible Suicides*	*Other*
Arizona	2	10	6
California	13	60	33
Michigan	3	26	10
Oregon	2	7	3
Pennsylvania	4	25	19
	24	128	71

Table 2

DISTRIBUTION OF LISTED CAUSE, OF DEATH REPORTS ON WHICH INTERVIEWS WERE COMPLETED

	Possible Suicides	*Suicides*	*Other*
Arizona	0	7	2
California	5	14	6
Michigan	2	7	3
Oregon	2	3	1
Pennsylvania	1	6	2
	10	37	14

National Incidence of Physician Suicide

Various studies going back as far as 1912, generally have placed the physician suicide rate between 30 and 40 per 100,000 population.[1] Given today's physician population of 461,000, a total of 138 to 184 suicides per year could be expected.

Extrapolations from the pilot study, however, yield a far smaller estimate of the number of physician suicides—approximately 90 per year (See Table 3 D). Even using a broader definition of suicide to include physicians whose deaths may or may not constitute intentional self-destruction, extrapolation falls below the above range-131 per year (See Table 3 E).

Thus, the extrapolated physician suicide rate for 1980-81 is 19.5 to 28.4 per 100,000. However, because the calculations were based on a relatively small sample of interview outcomes on "possible" suicides in the pilot states (37 of 128), the actual incidence of suicide is more likely to be higher than these estimated figures, rather than lower. It is reasonable to expect that a larger proportion of actual suicides were included among the deaths for which interviews could not be arranged, than among those for which interviews were secured.

For 1980, the national suicide rate for the entire U.S. population was estimated at 12.7 per 100,000—about a third of the traditional rate for physicians.[2] For comparison purposes, however, adjustments need to be made for age and sex. In the period of 1967-1972, for example, the suicide rate for white males over 25 years of age in the general population was 34 per 100,000, while the rate for male physicians was calculated to be 36 per 100,000.[3]

Table 3

EXTRAPOLATIONS, FROM PILOT STUDY, OF NATIONAL INCIDENCE OF PHYSICIAN SUICIDE

A.	Listed Suicides for 1980-81*		
	Pilot States	24	
	Other States	72	
	Two-Year Total	96	
B.	Possible Additional Suicides for 1980-81**		
	Pilot States	128	
	Other States (Est.)	384	
	Two-Year Total	512	
C.	Possible Suicides Identifiable as Actual Suicides***		
	Pilot States (Est.)	21	
	Other States (Est.)	62	
	Two-Year Total	83	
D.	Listed Plus Identifiable Suicides +		
	Pilot States (Est.)	45	
	Other States (Est.)	134	
	Total	179	(89.5 per year)
E.	Listed Plus Identifiable Plus Questionable Suicides + +		
	Pilot States (Est.)	66	
	Other States (Est.)	196	
	Total	262	(131 per year)

* As posted in AMA death records.

** Estimate for other states based on ration of "possible" to "listed" suicides in pilot states—5.33:1.

*** Estimates based on proportion of "possible" suicides in pilot states that were confirmed as suicides through interviewing—13.5%.

+ Estimates consist of sums of A and C.

+ + An additional 16.2% of "possible" suicides in pilot states remained questionable after interviewing. This additional number was added to the estimates in D to arrive at the estimates in E.

Selected Characteristics of Suicided Physicians

Retrospective analysis based on interviews of relatives and associates of 15 of the physicians who took their own lives reveals no unexpected differences between the life courses of these physicians and of 36 physicians who were perceived to have died of natural causes. There were unexpected similarities, however.

No substantial difference, for example, was found in use of alcohol or other drugs between the "suicides" and the "naturals." Although 26% of the suicided physicians and only 8% of the other group were reported to have been increasing their drinking at time of death, other evidence of disproportionate drinking was not apparent among those who suicided. Thus 27% of the "suicides" and 36% of the "naturals" drank daily, and only 13% of the "suicides" and 19% of the "naturals" ever drank more than they did at the time of their death. And in the family's attitude toward the physician's drinking, only 7%, or one family, expressed disapproval in the suicide group, whereas 14% expressed disapproval in the other group.

Another area where "suicides" did not differ from "naturals" was in their tendency to overwork. Half of all the deceased physicians, regardless of the cause of their death, were deemed to be "workaholics" by their spouses and others who were interviewed.

Suicides did manifest special vulnerabilities and were seen to have experienced events and circumstances which were not characteristic of physicians who died of natural causes. Eighty-six percent of the "suicides," for example, sustained personal and professional losses in the immediate past, but none of the "naturals" did.

With respect to financial matters, 60% of the "suicides" and only 22% of the "naturals" were said to have been "financially worried." A third of the"suicides" and a fourth of the "naturals" had some appreciable trouble in their practice, such as malpractice claims, but whereas all of the "suicides" who had such trouble either lost their licenses or hospital affilitations, none of the "naturals" did.

Half the "suicides" and half the "naturals" were said to have been practicing competently at time of death, but 20% of the "suicides" and none of the others were viewed as practicing incompetently. In their attitude toward patients, 73% of the "suicides" and 97% of the "naturals" were called "responsible," and 13% of the "suicides" and none of the others were termed "mildly irresponsible."

There were even greater differences in attitude toward their own medical careers: 20% of the "suicides" and 52% of the "naturals" were "deeply satisfied" with their careers, and 13% and 30% respectively were "content," but 33% of the "suicides," and none of the "naturals," were said to have been "bitterly dissatisfied." Only 33% of the "suicides" as opposed to 78% of the "naturals" were seen as being cooperative with colleagues.

In their marriages, "suicides" differed from "naturals" in how they derived satisfaction. For "suicides," the family was a source of satisfaction in only 13% of the cases, whereas recreation, and often isolated recreation, was the source in 27% of the cases. For "naturals," the corresponding proportions were 30% and 3%.

Respondents were asked whether they believed the suicide deaths were foreseeable or preventable. In 53% of the cases, they were "definitely" foreseeable and in 33% of the cases "possibly" foreseeable. But, while 60% were viewed as "possibly" preventable, only 7%—one case—was apparently "highly" preventable. If the physician had been in psychiatric treatment, foreseeability was substantially increased especially if there was hospitalization for depressive illness. Preventability, however, remained low.

Of principal suicide clues, mood was cited most often—in half of the cases. Word and work habits were each monitored in 19% of the cases.

Comments from interviewers after they had talked with respondents helped illuminate some of the pre-suicidal behavior and circumstances in the tragic lives of physicians who kill themselves.

Self-imposed isolation on the one hand, and overwork and overinvolvement on the other, were seen as two different mechanisms for attempting to cope with similar feelings of inadequacy and low self-esteem, or of fear of becoming deeply involved in interpersonal relationships. In such cases, in fact, working long hours, rather than leading to exhaustion, despair and suicide, may be a sustaining lifeline to which the physician clings for meaning and a degree of satisfaction in his existence.

Interviewers also commented that psychiatric treatment alone, or at an earlier time of life, does not seem to necessarily protect against suicide. If anything, the information indicated that therapists, colleagues and family need to be much more vigilant about this danger, more aware of the importance of support systems while the physician is in treatment. Too often friends and family members seem to believe that because "he's seeing a psychiatrist, we don't have to be concerned or bothered with him any longer."

Yet, there were too few cases of suicide investigated to draw more than a sketchy outline of a suicidal physician profile. A more complete picture would require interviewing on additional cases of physician suicide, together with in-depth analysis and correlation of both existing and new data and other information. The information at hand is suggestive at best. It does indicate, in summary, that being depressed, having financial problems, experiencing major personal or professional losses, being dissatisfied with professional life, having a less than responsible attitude toward patients, being uncooperative with colleagues, and deriving little satisfaction from family relationships, can be signals of impending suicide. A physician who sends out more than one of these signals may well be a candidate for prompt collegial concern and meaningful offers of help and support.

Physicians with Lethal Lifestyle

As already indicated, interviews following up 37 deaths that were adjudged to be possible suicides resulted in reclassifying six of the deaths as definite suicides.

In six other cases, however, doubt still remained, and in the aggregate they reflected a kind of chronic syndrome or sustained behavior pattern that might be characterized as a lethal lifestyle—perhaps near the center of a continuum running from unconscious or subconscious self-destructive behavior on the one end to suicide on the other.

The Need of Surviving Spouses for Therapy and Support

Suicides and other "needless" or sudden deaths usually exact a heavy psychological toll from those close to the deceased. Spouses especially need support and assistance as they attempt to work through a complexity of feelings of grief, shock, rage, guilt and disbelief. Time and again, this need was evidenced during the course of the interviews.

Process Issues

Where their involvement was adequately structured, AMA Auxiliary units proved to be valuable in locating next-of-kin for interviewing. The original plan to ask Auxiliary members to introduce the interviewee to the interviewer, however, did not work well because in many cases the surviving spouse had not been a member of the Auxiliary, or because the complexities of locating survivors and persuading them to be interviewed were too demanding.

Reluctance of spouses to participate in the project did not necessarily depend on the nature of the death. It was often as difficult to secure an interview with the widow of a physician who died of natural causes as it was with the surviving spouse of a suicided physician. Resistance did appear to be related to the time elapsed since the death occurred—for some, too much time had gone by, and for others, the death was too recent to discuss. (Optimal post-death intervals for interviewing seemed highly individualized.) Concern over confidentiality was not a major factor.

A useful approach to survivors appeared to be along the lines of the following: "I'm going to be calling on you in a while to learn about your husband's death and to see what further contribution we can make from his life in medicine to an understanding of why doctors die too young." The idea of contributing from a life that already had been lived seemed to mollify anger and resentment.

Of those survivors who agreed to be interviewed, the great majority believed the process was a valuable experience for them, even if somewhat stressful and tiring. On the whole, they appeared to be grateful for the experience. Only a few respondents, in addition to some of the interviewers, commented about the length and comprehensiveness of the interview; the average duration was three hours.

The psychiatrists who served as managers in the five states found that they as well as interviewers were required to spend a considerable amount of time in locating survivors, especially in remote areas and when next-of-kin information was not available from the AMA. The managers devoted additional time and effort to recruiting and orienting interviewers and keeping in touch with them on their progress, often at some expense to their own professional and family duties.

The questionnaire used in the interview process was also criticized by some interviewers and respondents for certain redundancies and duplications, and changes were suggested to expedite any future studies.

Some interviewers found the length of the questionnaire to be an obstacle to obtaining the kind of in-depth interview that a more simplified instrument might have made possible. Yet others were reluctant to shorten it if it meant sacrificing the uniformity that a structured questionnaire can confer on the interview process.

Physician Mortality in the Pilot States

More than half the deaths of physicians in the five pilot states, posted in AMA records in 1980 and 1981, were due to heart disease and cancer. (See Table 4.) The percentage of deaths caused by these two disorders was fairly uniform from state to state, although in Michigan proportionately more deaths were attributed to heart disease and fewer to cancer.

(Cause of death in nearly all cases was determined through information supplied by surviving spouses or other relatives, friends and newspaper obituaries. It is probable that this type of reporting would yield a higher number of immediate or acute causes, as opposed to underlying causes. In the small number of cases where death certificates were available in AMA records, for example, arteriosclerosis or atherosclerosis was listed as the underlying cause for 25% of the deaths, about five times the proportion attributed to this cause among the total number of deaths.)

Table 4
1980-81 PHYSICIAN DEATHS IN PILOT STATES, BY CAUSE

	Arizona	*California*	*Michigan*	*Oregon*	*Pennsylvania*	*Total*
Heart Disease	31	210	71	23	114	449
Cancer	20	147	20	11	74	272
Cerebrovascular Disease	6	44	9	4	31	94
Accidents	5	25	7	2	8	47
Arteriosclerosis/Atherosclerosis	6	32	13	1	14	66
Diabetes	1	2	2	1	0	6
Chronic Obstructive Pulmonary Disease	2	22	5	1	13	43
Pneumonia/Influenza	6	26	0	2	5	39
Chronic Liver Disease	1	5	2	0	1	9
Homicide	0	3	0	0	0	3
Nephritis/Kidney Disease	0	10	4	0	5	19
Septicemia	1	7	1	1	1	11
Suicide	2	16	4	3	5	30
Other or Unknown	6	82	19	13	50	170
TOTALS	87	631	157	62	321	1,258

Among the specialties, surgery, obstetrics and gynecology, and ophthalmology shared the highest percentage of deaths due to heart disease. (See Table 5.) Anesthesiology had the lowest for heart disease, and, along with radiology, the highest for cancer. Family practice, obstetrics and gynecology, and surgery had the lowest percentages of cancer deaths. In cerebrovascular deaths, public health, pathology and pediatrics ranked highest, and psychiatry-neurology and radiology ranked lowest. The small sample of 30 suicides does not lend itself to generalization about the relative suicide risk among the specialties.

Female physician deaths—totalling 67—likewise were a small sample among the 1,258 posted deaths. Nineteen, or 28%, of the female physician fatalities were attributed to cancer, 22% to heart disease and 12% to cerebrovascular disease. These compare with 22%, 36% and 7% respectively for the entire cohort. Of the 30 suicides identified, 3 were women—about twice the proportion for men: in other words, there were 17.8 male deaths for every female death, but only 9 male suicides for every female suicide. Again, generalizations to the entire physician population are inappropriate because of the small numbers involved, although these results are consistent with findings in several other studies.[4,5,6]

Has physician mortality changed appreciably over the years? A comparison with 30 years ago indicates that it has. Dickinson and Martin[7] made an intensive study of 10,738 physician deaths that occurred from 1949 through 1951, and looked especially at causes and age groups. Similar data for 1981, taken from the current pilot study, afford a perspective on incidence and causality. (See Table 6 and 7.)*

Table 6
30-YEAR COMPARISON OF CAUSES OF PHYSICIAN MORTALITY

	1949-51 [a]	*1981* [b]	*1949-51* [a]	*1981* [b]
	(%)	*(%)*	*(Rate per 100 M)*	*(Rate per 100 M)*
Heart Disease	49.0	38.9	858.7	280.9
Cancer	14.3	22.5	249.7	162.5
Cerebrovascular Disease	11.2	8.5	196.0	61.3
Accidents	4.6	3.2	79.7	23.2
Arteriosclerosis	1.9	5.5	33.9	39.9
Diabetes	1.9	0.5	32.9	3.7
Suicide	1.8	2.6	31.1	18.8
Influenza/Pneumonia	1.5	4.0	26.2	28.8
Kidney Disease	1.2	1.3	21.4	9.3
Liver Disease	1.1	0.6	19.6	4.6
Tuberculosis	1.1	0.0	19.4	0.0
All Other Causes	10.4	12.4	182.5	89.1
Totals	100.0	100.0	1751.1	721.6

[a] Adapted from Dickinson and Martin.[7] Rates cited are annual averages for the three-year period.

[b] Based on reports of deaths posted in AMA records for 1981 for the five pilot states.

Annual death rates per 100,000 physician population were lower in 1981 than in 1949-51 for all causes except influenza/pneumonia and arteriosclerosis. The reductions were most pronounced for tuberculosis and diabetes. The rate for heart disease dropped 67.3% and for cancer 34.9%. Overall the physician death rate fell 58.8% in 30 years—from 1751.1 per 100,000 to 721.6 per 100,000 (See Table 6.)

Table 5
COMPARISON OF SPECIALTIES IN CAUSES OF DEATH, 1980-81*

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	# *Deaths*
Anesthesiology	25.0	34.4	12.5	3.1	3.1	3.1	3.1	3.1	0.0	0.0	0.0	0.0	0.0	12.5	32
Dermatology	35.0	25.0	10.0	5.0	5.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.0	20
Family Practice	31.4	14.3	8.6	11.4	5.8	0.0	2.9	8.6	0.0	0.0	2.9	2.9	0.0	11.4	35
General Practice	37.4	23.3	6.7	7.0	1.9	3.7	2.6	0.7	2.2	0.7	0.0	0.0	0.0	13.8	270
Internal Medicine	33.9	20.8	5.5	5.5	7.1	3.3	2.7	2.7	1.1	0.0	1.1	0.5	0.0	17.5	183
Obstetrics/Gynecology	39.2	19.0	5.1	3.8	8.9	3.8	3.8	3.8	1.3	1.3	0.0	0.0	0.0	10.1	79
Ophthalmology	38.3	25.0	5.0	3.3	3.3	8.3	5.0	0.0	1.7	1.7	0.0	0.0	0.0	8.3	60
Pathology	37.0	22.2	14.9	0.0	0.0	0.0	3.7	3.7	0.0	0.0	0.0	0.0	0.0	18.5	27
Pediatrics	39.7	22.7	13.2	1.9	1.9	1.9	0.0	0.0	1.9	1.9	0.0	1.9	0.0	15.1	53
Psychiatry/Neurology	32.2	24.1	3.4	2.3	4.6	3.4	2.3	3.4	1.1	2.3	3.4	0.0	2.3	14.9	87
Public Health	35.8	21.4	35.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	7.1	14
Radiology	34.5	31.0	3.4	0.0	3.4	0.0	0.0	3.4	3.4	3.4	0.0	0.0	0.0	17.2	29
Surgery	39.9	19.6	7.7	5.4	3.8	1.8	2.4	4.8	0.6	1.2	1.2	0.6	0.0	11.4	168
Other	35.0	20.4	10.2	5.1	1.3	3.2	5.7	0.6	2.5	0.6	0.0	0.6	0.6	14.0	157
Unspecified	25.0	9.1	2.3	13.7	6.9	9.1	6.9	9.1	2.3	2.3	0.0	2.3	0.0	11.4	44
Total	35.7	21.7	7.5	5.2	3.7	3.4	3.1	2.4	1.5	0.9	0.7	0.5	0.2	13.5	1258

* For Deaths Posted in AMA records in 1980 and 1981 for the States of Arizona, California, Michigan, Oregon and Pennsylvania. Figures in numbered colums are the percentages of total number of deaths for each specialty attributed to each cause. Causes are as follows: (1) Heart Disease, (2) Cancer, (3) Cerebrovascular Disease, (4) Arteriosclerosis/Atherosclerosis, (5) Accidents, (6) Chronic Pulmonary Disease, (7) Pneumonia/Influenza, (8) Suicide, (9) Nephritis/Kidney Disease, (10) Septicemia, (11) Chronic Liver Disease, (12) Diabetes, (13) Homicide, (14) Other or Unknown.

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*(It should be emphasized that the two studies are not comparable in all respects. The earlier study comprised all U.S. physician deaths for that period and relied almost entirely on death certificate information whereas the current study, as mentioned earlier, rarely involved death certificates and included physician deaths in only five states.)

Table 7

30-YEAR COMPARISON OF PHYSICIAN MORTALITY, BY AGE

Age	Average Annual Death Rate Per 100 M 1949-51 [a]	Extrapolated Annual Death Rate Per 100 M 1981 [b]	Ratio 1949-51:1981
Under 35	13.6	3.3	4.12:1
35-44	30.1	5.4	5.57:1
45-54	91.1	54.6	1.69:1
55-64	288.7	122.0	1.87:1
65-74	499.9	229.1.	2.18:1
75 & Over	1082.8	682.5	1.59:1

[a] Adapted from Dickinson and Martin.[7]

[b] Based on reports of deaths posted in AMA records for 1981 for the five pilot states.

A comparison of death rates by age group shows that proportionately four times as many physicians under 35 died in 1949-51 as in 1981, and nearly six times as many aged 35-44. By contrast, the ratio in the 65 to 74 age category was only 2.18:1, and only 1.59:1 for physicians aged 75 and over. (See Table 7).

Thus, not only fewer physicians per 100,000 were dying in 1981, but they were dying at an older age. Whereas 66.2% of physicians who died 30 years ago were 65 and over, 71.4% of the deaths occurred in this age group in 1981. The difference is even larger for physicians who died at age 75 or over—35.6% of the deaths occurred in this category 30 years ago, as opposed to 42.1% in 1981.

The total U.S. physician population was younger in 1980 than in 1950. However, in 1980, 28% of all physicians were under 35, compared with 25% in 1950. Those 65 and over constituted 14% of all physicians in 1980, down from 16% in 1950.[7,8]

Recommendations

Based on the above findings, the Council on Scientific Affairs recommends that:

1. The Physician Mortality Study be extended through Fiscal 1984.
   a. The compilation of physician deaths for 1980 and 1981 in the five pilot states should be analyzed epidemiologically and age-adjusted for additional comparisons with physician deaths of 30 years ago and with deaths in the total population of the United States.
   b. Additional interviews should be sought to expand the relatively small information based on physician suicides. All physician suicides posted as such in AMA death reports for 1981 through 1983, as well as deaths falling in the probable range and deaths of medical students, should be reviewed for possible interviewing of next-of-kin or other survivors. It is estimated that a total of 100 such interviews could be conducted nationally in 1983 and 1984. The possibility of interviewing a small number of physicians who have attempted suicide and survived the attempt also should be explored.
   c. The cooperation of the APA and its District Branches again should be sought as needed in recruiting selected volunteers to interview in those parts of the country where physician suicides are identified. The APA already is in the process of organizing volunteers to study suicides among psychiatrists nationally.
   d. Administrative matters associated with the interviewing process should be handled by the AMA, including transmittal of death reports and questionnaires, communications with interviewers, and identifying and locating prospective interviewees.
   e. The Panel on Physician Mortality should oversee a revision of the questionnaire used in the pilot project, based on experience and professional critiques. The questionnaire should be shortened, simplified and made more amenable to quantification of data.
   f. The Panel on Physician Mortality should designate selected deaths from the pilot study that warrant furter exploration and perhaps re-interviewing, especially deaths in the suicide and lethal life-style categories.
2. With a view toward publication, qualified researchers be encouraged to explicate and elucidate the key issues emerging from the pilot study. Participants in the pilot study should be given priority in this regard. Opportunities for further study by re-interviewing, by accessing existing pilot study information and by other means, include the following areas:
   a. Predisposing biological, psychological and social factors in physician suicide.
   b. A physician-suicide "profile."
   c. Physicians with lethal life-styles.
   d. The professional life of the suicidal physician.
   e. The family-life of the suicidal physician.
   f. Positive and adverse influences of the medical

education process and environment on physician suicide.

   g. Implication of the pilot study findings for effective identification and treatment of pre-suicidal physicians.

3. Foundations and other funding sources be encouraged to support these and other worthwhile investigatons.
4. The AMA, through appropriate units, urge the undertaking of activities and program modifications which studies show can help reduce the incidence of physician suicide.
   a. Medical schools and physician training programs should become more cognizant of the importance of students fulfilling their personal and social needs. Successfully meeting these needs can promote health and prevent suicide and other forms of premature death. In this regard educators also should facilitate the creation of self-help and other support groups among students.
   b. State and county medical societies, specialty societies and hospitals that have impaired physician programs should be encouraged to become more alert to the psychiatric problems of troubled colleagues and assure early therapeutic intervention. They also should intensify their efforts during the impaired physician's recovery period to break down barriers of stigma and prejudice that too often isolate or hinder the rehabilitated physician who attempts to return to practice.
5. In any future study, interviewers be asked to be of assistance in arranging for needed emotional support for surviving spouses, and the AMA Auxiliary be encouraged to explore the formation of "widow-to-widow" outreach programs for spouses who may feel alone and abandoned.

The AMA is indebted to the Panel on Physician Mortality and to the APA and the 135 psychiatrists who volunteered to take part in the pilot study.

A debt of gratitude is owed as well to the surviving spouses and other relatives and colleagues of deceased physicians, who participated fully and generously in the hope that others might live longer and happier lives.

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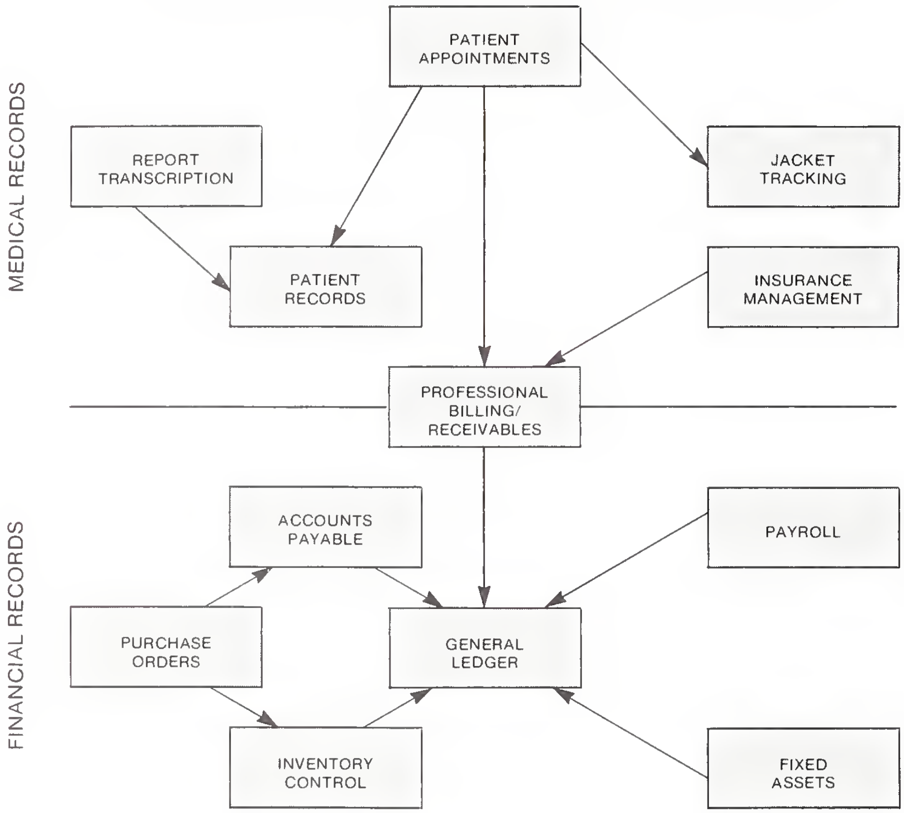

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How Your Practice Can Cope with Change

LEIF C. BECK, LL.B., CPBC, GEOFFREY T. ANDERS, J.D., CPA, CPBC,
AND DOROTHY R. SWEENEY

While so much is written these days about the future of medical practice, many physicians seem to ignore clear indications of change. This may be understandable in view of their continued clinically and financially rewarding practice situations. After all, who wants to give up a good thing merely because of predictions that things may change? "If it ain't broke, don't fix it," goes a popular saying.

That saying may be fine for a doctor who has worked hard to build a very good practice; he or she can probably ride out the era of change, though quite possibly with declining income, for five to ten years. If, however, the doctor is between age 30 and 50 or cares enough to assure continued practice success indefinitely, the changes in medical practice must be considered and accommodated.

At a recent seminar, one speaker made the following point: *"The best way to manage change is to anticipate it."* We consider this statement to be absolutely essential advice for physicians who want their practices to survive indefinitely. Since changes are so obviously under way, and much more change will come, physicians should stay closely attuned to what will probably happen.

General Conditions

With this background, here are our views on the direction of medical practice. They are not comforting to doctors who are emotionally or financially committed to the way things have been, but we believe these directions are virtually unalterable.

Capacity to Pay: Perhaps most significant of all, there is a clear squeezing of our national capacity to pay for the level of health care which the public has come to expect. The "entitlement" thinking of the 1960's, when the nation seemed wealthy enough to afford all sorts of benefits, has shifted to the 1980's—when our national wealth has essentially levelled off. Health care is buffeted within this much greater economic/sociologic fact, and one cannot assume any solution allowing constant growth.

Thus we have seen the beginnings of approaches designed to limit health care expenditures. DRGs and the recently enacted freeze on physicians' Medicare fees are clear examples of such efforts, as is governmental support and encouragement of alternative delivery systems such as HMOs.

Who knows what will be the next, possibly much more permanent, proposed "solution" to the economic squeeze? Perhaps capitation (payment per patient rather than per procedure) will be imposed on doctors' services. Perhaps uniform fee schedules will be imposed by the federal government, and/or by insurers and employers, just as we are already encountering a national schedule of lab fees.

We consider one development nearly certain. The fees paid for "non-cognitive procedures" will decrease significantly, since virtually all segments of society seem to agree that procedure fees are far too high. Open heart surgery, intraocular lens implantations, cardiac catheterization and fiberoptic procedures are examples of allegedly "overpriced" services.

Government Pressures: Many people predict a continued growth in governmental regulation of private medical practice, we see it a bit differently. We instead expect government's effort will be to create the conditions that will make medicine less rewarding economically. DRGs, fee schedules, HMO support and "all payers" limits on reimbursement levels are not so much regulation as they are pressures on practice economics.

Regardless of what one calls it, however, government is the "big daddy," directly and indirectly influencing doctors' incomes. There is little hope of effectively curbing that influence by court action, for physicians hardly have a constitutional right to their economic well-being. If government can regulate banks, control natural gas prices and impose laws on corporate take-overs—all of which are understood to be for the public's benefit—it can also affect medical economics.

Increasing Supply: Like another arm of the pincer, these restrictions on the *demand* for medical services come at

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The authors are the principal consultants and attorneys of The Health Care Group, Bala Cynwyd, Pennsylvania.

a time of tremendous increase in the supply of those services. The number of physicians in practice now is vastly higher than before and the predictions for 1990 project a still higher number. While doctors tended to dismiss the projections just a couple of years ago, almost all of them now see the continually increasing number of "colleagues"—or "competitors"—in their specialties.

The pincering effect means that conflict is virtually inevitable at the physician level. It will probably result in the virtual annihilation of some ancillary medical occupations such as physicians' assistants, respiratory therapy and the like; doctors may be happy to do the work of those people in view of the available time and the need for income.

Resulting Competition: These various circumstances certainly show why competition among medical providers is becoming rampant. The pincers of a shrinking pot invaded by a growing number of fingers virtually preordain such competition no matter how noble the profession may be.

Much of the competition comes from so-called alternate providers. HMOs are developing virtually everywhere; physicians, in town after town, hold discussion sessions to consider how they should cope with actual or rumored HMO incursions. HMOs now have some 20,000,000 patients and are predicted to have 50,000,000 by 1993. That's a lot of patients chopped off private practices' rolls.

The convenience facilities ("urgicenters," and "immediate care centers," among other titles) are also doing quite well. We know of some practices badly affected by the expanded hours and aggressive marketing which nearby facilities feature. Those new facilities are providing a feature important to consumers these days—"convenience".

Hospitals are themselves delving more and more into medical practice even though it may be technically illegal. In their battle to survive, vertical integration of health care services becomes one of their possible salvations. And that integration injects hospitals right into the privately practicing physicians' turf.

But physicians' main competition comes from other physicians. Specialty-crossing is rampant as doctors seek to provide more services that might maintain their incomes: witness allergy and facial plastic surgery. Advertising is on the rapid rise and will almost inevitably continue to grow. And as "premier groups" contract for bulk patient care (discussed later), the patients gained are lost by other privately practicing doctors.

Antitrust Law: A prime example of inter-doctor competition and turbulence is baring itself these days. Medicine has entered the business world enough to be the hot topic in antitrust law.

Medical staff admission and privileges are vital issues for doctors on both sides—both the "ins" and those who seek to be "in." There are a number of cases which are widely known to lawyers and physicians. These cases involve millions of dollars in legal fees as well as untold potential liability if they are ultimately decided in favor of the plaintiffs involved.

Even though hospitals are co-defendants in these various lawsuits, physicians may themselves be at risk. In fact, since their medical staffs may be held liable separately from their hospitals, it is becoming essential to legally separate and incorporate the staffs. Doctors can no longer hide behind their hospitals' skirts.

Antitrust law arises in non-hospital practice situations as well. For example, while we have participated in more group mergers than ever before, some of these joinders touch the ill-defined, and still rather conjectural, antitrust rules as they might apply to health care. And yet antitrust suits are so expensive and, if lost, so economically devastating, that doctors cannot take chances. Physicians are in the "big leagues" of business when those laws are involved.

Our Prescriptions

What should the currently successful practicing physician do given this rather bleak description? Except for those who elect to ride their practices out for five or ten years, probably with declining patient volume as they move to retirement, we believe doctors should emphasize our opening key statement: *"The best way to manage change is to anticipate it."*

The changed conditions offer opportunities as well as problems. In the airline and steel industries, some companies are suffering and even dropping out while others take advantage of the conditions. We see the same scenarios in medicine, for some practices are growing and prospering despite the conditions. They have adapted to the changed game while still giving the same high quality medical care.

Here are some of the major approaches and basic philosophies we believe are essential for such success.

Business Planning: Doctors tend to resist the idea that hard-headed business planning makes sense in their professional practices. It cannot, however, be disregarded and it cannot be done half-heartedly.

The first part of business planning is to identify the broad goals and how they fit into both present structure and projected financial resources. The goals cannot be all-encompassing, for we find it necessary these days to establish areas of preeminence, even if other areas must be abandoned. For example, internists may have to decide if they are to be primary care doctors or referral specialists; it is becoming harder to be in both camps and prosper in either one.

As to the finally agreed planning document, there must be a reasonable consensus among the practice's players. In a solo practice, at least the manager and key staff members should accept the goals, while all physician-members of a group practice should be comfortable with the major directions. Those who are unwilling to accept and work within the business plan's broad goals should probably not stay with that doctor or group. Interestingly, business plan goals tend to be self-fulfilling to the extent that people's day-to-day actions reflect those goals.

Second, from the broadly stated plan should come specific strategies, to be followed in order to achieve the goals. What steps should be taken, – moving one's office, replacing certain personnel, promoting certain aspects of the practice or opening a satellite office? And on what timetable?

As an example of this second phase of business planning, we recently followed up on a survey we had performed for a larger group practice six months earlier. The managing partner reported that the group had identified six primary goals and then set out over *sixty* specific actions to be taken. The likelihood of actually achieving their broadly stated purposes should be distinctly greater with that 60-item action plan in place.

Market Share: Given the competitive threats and the uncertainties for the next few years, we are urging an emphasis on "market share" – a practice's volume of patients as measured against the total available volume. This is not the time to lose patients, for we expect the next few years to be tolerable mainly for those doctors who have a large market share.

The larger number of patients will enable a practice to keep its income up as well as possible if the fees begin to drop. Market share will certainly permit maximum possible income if the system shifts over to a capitation (payment per patient) basis. And as we see doctors and groups negotiating with hospitals, HMOs and directly with employers, a larger volume practice should translate to greater negotiating strength.

Therefore, even if a physician must accept a lower fee on some current patient work, the lesser payments may be preferable to losing those patients – to losing "market share." We have therefore generally favored participation in HMOs and PPOs as a means of holding onto patient volume rather than ceding the work to others. We also encouraged participation in Medicare unless the financial circumstances were too adverse; those doctors who elected not to participate now face the risk of adverse publicity and a possible decrease in patients.

Marketing Emphasis: Closely related to the "market share" point, the entire field of marketing has become a key element in one's practice. Marketing is, however, a far broader term than mere public relations and advertising. It involves attention to one's business from the other person's – the consumer's – point of view.

One attribute of successful business corporations is that they are "consumer driven." They focus on anticipating and selling what the consumer *wants and needs,* rather than on selling what they (the sellers) want to sell. Most major new products and services originate this way – from identifying the potential buyer's preferences rather than seller's interests.

But how does being "consumer driven" apply to physicians? As one example, we believe that health care consumers are in large part business employers, labor unions, insurance companies and the government – not individual patients. These organizations are purchasing most of the health care which physicians provide through patients. The one thing these major purchasers must have is a basically controllable and definable cost structure consistent with quality service.

Unfortunately, physicians have notoriously resisted adapting to this need, equating cost controls and fee restraints with compromises on quality of care. The better approach would be to seek ways to assure the big purchasers about their expense levels while maintaining normal emphasis on quality. If this means that a doctor or group might have to accept less than full fee work in order to serve a larger block of patients, that should be a *good* step.

Another example involves a demographic characteristic sometimes called the "nocturnal market." Goods and services are increasingly being demanded outside the traditional "9 to 5" hours. The banking industry has recognized this characteristic in a unique way, establishing automated teller machines which make bank services available 24 hours a day, seven days a week. Physicians, however, are only now beginning to shift to evening and weekend office hours. Not being consumer driven, private practitioners have preferred office hours that suited their busy lives, and until recently they had been able to call the tune.

Group Practice: Unfortunately, we do not see solo practice as the way to cope with change over the long run. We have in fact predicted that there will be significantly fewer solo and even small group (two to five doctors) practices about ten years from now.

The trend towards larger practices, both single and multi-specialty, is already apparent. Groups can better allocate physician time to early mornings, late evenings, weekends and holidays than can a solo; one physician simply cannot be available all the time, but a ten-doctor group can easily provide convenience center hours.

The larger group can also spend more meaningful dollars. It can afford to hire a high-salaried administrator with an MBA degree to help steer it through complex contract negotiations. It can purchase state-of-the-art medical equipment to keep it on the cutting edge of its specialty. And it can maintain a large enough p.r./advertising budget to bring in additional patients, while solos spending small amounts may be unable to dent the ad market.

We expect groups to jump in size from three to six doctor sizes up to 10 and 15 members over just the next few years. But all the practices in a service area cannot grow. In fact, the opportunities to establish the described advantages will probably arise just once in each specialty in each community. Once a group has done so, there will probably not be room for its competitors to adapt.

Physician Leadership: One factor in practice management never changes. Whether solo practice or group (large or small), there must be effective leadership at the physician level. Success emanates from a doctor-owner's ability to set the proper tone for the entire practice; conversely, we often point out that every failure or weakness can and should be the fault of the practice's "CEO"—its chief executive officer, or the doctor in charge.

For the sole practitioner, he or she must first identify the practice's characteristics and assure that everyone concerned will conform to them. This CEO-physician must create a consistent atmosphere so the lay staff will act according to the selected goals. Planning and strategy are useless if the doctor-leader cannot, or will not, cause all concerned to act consistently with the business plan.

We find that group practices, even if just two or three doctors, require a strong and capable leadership format to accomplish what is within reach. The most desirable structure is for a single "CEO," just as other businesses thrive or fail because of their leadership. In some practices, however, where no single physician-member fits the CEO slot, a different leadership model may be necessary. This will usually be a two or three-doctor "executive committee" specifically authorized to act as though those two or three people were, together, an individual-in-charge.

Businesses do not survive these days without good leadership, and medical practice is becoming more like other businesses. Doctors wishing to adapt to the changing health care scene need a leadership format—usually a "CEO"—in order to cope.

Conclusion

As described, the circumstances for privately practicing physicians are less favorable than anytime in the past twenty years. The health care industry is not, however, alone in encountering new, rapidly changing problems. As in other business situations, these problems create opportunities as well as annoyances. Thus we see some doctors making their practices prosper within the parameters of quality patient care by being alert to the circumstances and applying modern management skills to take advantage of them.

These successful practices realize the best way to manage in a changing environment is to anticipate and face the change head-on.

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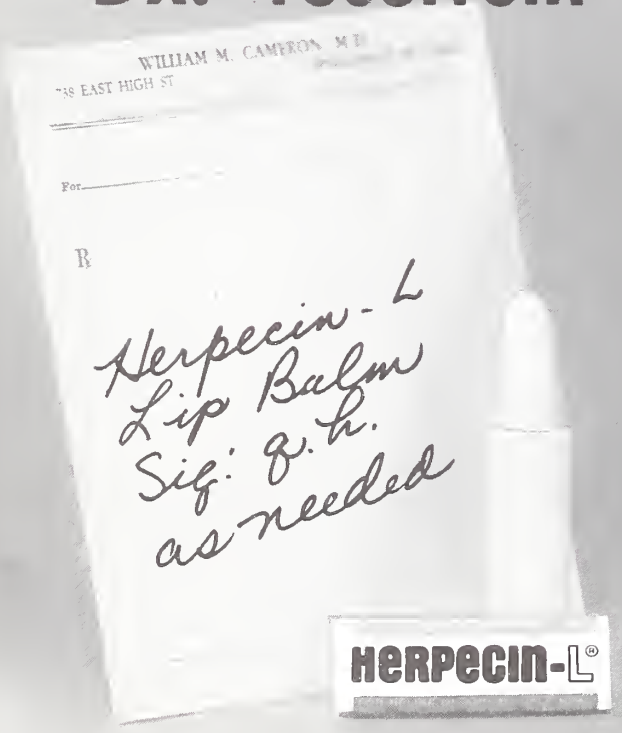

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The President's Page

"The Clock Is Striking Thirteen"

Is the present regulatory process intimidating medical decisions? Are we yielding to the influence of "Committee Medicine"? Who is "Big Brother" and is "he" influencing the environment of medicine? Are we in danger of losing our individual initiative and independence of thought? The answers to all these questions is "Yes."

It appears that pre-admission certification for all elective hospital admissions may ultimately be required by Third and "Fourth" party payors. The AMA is on record as being opposed to "blanket pre-admission certification" but recognizes the prerogative of physician sponsored peer review organizations to implement focused pre-admission review on a voluntary basis. Furthermore, the AMA Council on Medical Services recognizes that pre-admission certification, when properly administered as a form of peer review, may provide increased assurance of medical consensus as the proper treatment for a patient's condition. The Certificate of Need system, however, carries the possibility of inappropriate delay of ment and increased professional liability risk. Professional judgment may be unfairly second guessed, and further restraint will be placed on our professional independence. With each increase in the regulatory process, our individual initiative and independence of thought will be challenged.

Pre-certification for admission is a form of "Committee Medicine." "Committee Medicine" is beginning to emerge on a local level in our hospitals where committees and departments are voluntarily or unvoluntarily establishing guidelines or protocols to be applied to the treatment of various clinical entities. The inherent danger is that the guidelines and protocols might be inflexible and thus may not respect the variables which inevitably exist in the natural history of the disease process. Once again, our individual initiative and independence of thought will be compromised if these edicts are accepted unchallenged.

Definitions of "Big Brother" differ. The dominant force which has changed and will influence the Environment of Medicine in the future is the existence of the computerized data gathering networks which are presently being utilized by Third and "Fourth" party payors. The "Big Brother" of Medicine which is watching us is the *COMPUTER!* Corporations are in demand of physician specific utilization cost data. The analyses of these data become a "bargaining tool in establishing contract provider organizations." Involvement in "contract provider organizations" potentially produces loss of control of individual initiative and independence of thought and action.

We must remember that the disease process is a heterogeneous entity in a heterogeneous group of individuals. It is the responsibility of the physician and not the computer to decipher the complexity of clinical problems. Quality of care is vitally dependent upon the reliability of the physician to be dependably accountable to the patient and to himself while rendering clinical judgment to the best of his or her ability. Individual initiative and independence of thought must be preserved so that the physician can freely ask and act upon the question, "What is the best thing to do for this patient at this time?" The problem solving ability of the physician must not be disrupted or intimidated by the regulatory process, by mandated protocols, or by the intricate programs contrived as a spin-off of collection data systems. Otherwise, clinical results will be jeopardized.

George Orwell, in his book Nineteen-Eighty-Four, reminds us that "Big Brother is watching us, and the clocks are striking thirteen." If we are to survive as an honorable profession, we must, in spite of intimidation, continue to strive as patient advocates in constant pursuit of perfection in patient care in order to prevent "the clock from striking thirteen."

William A. Whalen, M.D.
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Reflections on Medicine

Osler's Bedside Library

ROBERT U. MASSEY, M.D.

Every few years someone rediscovers William Osler's "Bedside Library for Medical Students," and adds and deletes titles to bring it up to date. You will recall Osler's advice to medical students, many of whom, in 1904, were entering medical school directly from high school: ". . . try to get the education, if not of a scholar, at least of a gentleman." He recommended reading for half an hour before going to sleep, "and in the morning have a book open on your dressing table." His list for a bedside library reveals the sources for many of his quotations and allusions; you would expect to find these books at the bedside of an Edwardian gentleman; they would be pleasant to have within reach even today.

The University of New Mexico Medical Center Library recently sent around Osler's list to their medical school faculty and asked for new titles to "augment and update" the 81 year old bedside library. There were 59 new titles suggested and only three authors were mentioned more than once: Norman Cousins, A. Conan Doyle, and Lewis Thomas.

Those ten works of his reflected the classical education of the author of "Aquinimitas," the book which medical students used to receive upon graduation, courtesy of Eli Lilly and Company, and which introduced them to the great humanist physician. Four of the ten were from the ancient world: the Bible, Plutarch, Marcus Aurelius, and Epictetus; four from the late Renaissance and early modern period: Shakespeare, Montaigne, Browne, and Cervantes; there were only two 19th century authors, both American: Holmes and Emerson.

The New Mexico faculty selected almost half their authors from the 19th and early 20th century; these were books most of us had read in literature courses, books that were our classics and which we now discover that most medical students have not read: authors like Dickens, Dostoyevsky, even Faulkner and London. They did add some additional titles from classical times and the Renaissance: Plato, Hippocrates, Pare, and Machiavelli. Some showed a broader sweep than was characteristic of Victorian education: Veblen, Proust, Mill, Carroll. These would have been too modern for 19th century undergraduates. No one mentioned Darwin or Huxley; no one included George Eliot's "Middlemarch," a novel some of our students have newly discovered.

Inviting someone to submit a list of books "which everyone should read" is a way to discover which intellectual or popular fashions exerted the most influence, or, more likely, what literary traditions were in vogue in the schools he attended. When someone asks me to suggest titles for reading lists, many that come to mind are books which I ought to read but may never get around to.

Physicians may have a special need for authors who will become their *comes viae vitaeque,* helping them with their metaphysical anxieties without using metaphysical language. Pain, depression, dismemberment, and death, as well as the good things like birth, recovery, and resurrection, are better dealt with by story and poem.

"Even with the very greatest masters of the written word," Lucien Price comments in his "Dialogues of Alfred North Whitehead," "Dante, Goethe, Aeschylus . . . one is left aware of how pale the statement is in comparison with the experience itself." Later he adds, "What perhaps the written word *can* do is recall to us our own experiences, or give us intimations of experiences which we are likely to have." He then asks the 80 year old Whitehead, what comes through first from the great authors "as conscious experience?"

"The moral values, I should say," he replies, and later, "The aesthetic."

Osler would have hoped for the light touch in any case; he had his Sir Thomas Browne and quite possibly his Izaak Walton always with him; like his, their natures "all sloped toward the sunny side."

ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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Foregoing Artificial Nutrition and Hydration: In Search of a Public Policy

A series of well-publicized cases in California,[1] New Jersey[2] and Massachusetts[3] have focussed attention on the extent to which it is ethically and legally permissible to withhold or to withdraw artificial nutrition and hydration from critically ill patients. This question evokes a strong emotional response because of the perception that food is a fundamental aspect of living to which all are always entitled. Such perceptions fail to account for the distinctive characteristics of artificial nutrition which situate it among the many technological innovations which may either benefit or burden patients. In this and in subsequent columns I will explore these cases and their implications for the development of public policy in Connecticut dealing with this complex area of concern.

The California case was the first of the cases and involved the first reported attempt to use the criminal law as the basis for challenging the decisions of two physicians who withdrew nutrition and hydration from one of their patients. Clarence Herbert was a 55-year-old who required surgery for closure of an ileostomy. He suffered cardiopulmonary arrest in the recover room following successful completion of the surgery. He was revivied by a team of physicians and surgeons and placed on life support equipment. During the next three days, Mr. Herbert was judged by his physicians to be in deep coma with no reasonable likelihood of recovery. His wife and family requested that the machine sustaining his life be removed. When the respirator and other life support equipment had been removed, he continued to breathe, though he showed no sign of improvement. Two days later, after further consultation with the wife and family, the physicians ordered removal of the intravenous tubes which had provided hydration and nourishment. On the eleventh day following the original surgery and cardiopulmonary arrest, the patient died. Concern about events surrounding the patient's death led a nurse to notify the local district attorney who charged the physicians with the crimes of murder and conspiracy to commit murder. Attempts to have the charges dismissed by the magistrate were overruled by the Superior Court. The Court of Appeal was asked to review the Superior Court decision and concluded that the charges against the two physicians should be dismissed.

In its decision, the Court expressed its uneasiness in addressing the issues presented in this litigation. It emphasized that the only effective manner to deal with such issues was through legislative action. Nonetheless, legislative inaction left the Court no choice but to examine the conduct of the physicians within what was described as the "woefully inadequate" framework of the criminal law. The Court construed the central question to be whether the conduct of the accused was unlawful in managing care for a patient facing an indefinite period of vegitative existence without reasonable likelihood of returning to normal functioning. An acceptable answer to this question must take into account the right of the patient to accept or refuse treatment, the limits of medical technology, and the need to examine carefully the extent to which the proposed treatment is beneficial to the patient. In short, the Court concluded: (1) that there is a legally recognized right to refuse treatment possessed by patients; (2) that the use of intravenous nourishment and fluids under the circumstances should be treated in the same manner as the use of a respirator or other form of life support system; (3) that physicians have no duty to continue treatment once it is proven to be ineffective; (4) that the development of standards for the determination of when such a situation occurs and how and by whom such a determination should be made is the province of the legislature; (5) that in the case at hand, in the absence of legislative guidelines, applying existing relevant principles, the decisions were properly made, incorporating appropriate consideration of the patient's condition, the benefits and burdens of intravenous nutrition for this patient, and the wishes of the patient and his family; and (6) in summary, that failure to continue treatment under the circumstances of the case was not unlawful and was not subject to criminal sanction.

Though not a decision of the highest court in California, this decision represents a well-received first step in clarifying the doctor's duties in similar cases.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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FIRST THE VISION

To the Editor: I wonder if it was proper to let Dr. Massey use the pages of *Connecticut Medicine* to promote his "vision" of medical care (Conn. Med. 49,9;621.Sep.'85). Government employees paid with our taxes, as Dr. Massey is, would naturally like to see this centralized system prevail, but his subtle approach and false analogies may easily leave the reader confounded.

Doctor Massey begins by comparing *public education* to *public health*, both successfully managed by Government outside the market-place. Few of us argue against Government involvement in public health matters, such as sewers, immunization or labelling requirements. But when in the next part of his essay he subtly changes "public health" to "medical care" and "medical services," those who believe in a free society may wish to take exception. There is room both for public and for private education. Does Dr. Massey wish for Government control of Yale, Harvard, or Johns Hopkins? Is education there inferior to that at the University of Connecticut in Farmington? Similarly, there would seem to be room both for centrally controlled public-health and for the private delivery of medical services.

Doctor Massey's "vision" of the future mode of medical care delivery can scarcely be shared by many in our Medical Society.

Harry H. Mark, M.D.
Farmington, CT

The above letter was referred to Dr. Massey who offers the following reply:

The Editor: If Dr. Mark had read my "First the Vision" more closely, he would have discovered no details of the "vision" which he found improper for the pages of *Connecticut Medicine*, for indeed I did not attempt any more than a reference to "an idealized concept of what medical care should be," certainly no vision of any "centralized system" which he asserted that as a government employee, I "would naturally like to see."

We have, I am sure, misunderstood one another. My view of government interference, as many "Reflections" would attest, is closely akin to that of John Stuart Mill expressed in his essay, "On Liberty";[1] I suspect that Dr. Mark and I would find each other in full agreement with Mill when he wrote that government should refrain from doing anything "when the thing to be done is likely to be better done by individuals" especially since "there is no one so fit to conduct any business . . . as those who are personally interested in it." He added later that the "most cogent reason for restricting the interference of government is the great evil of adding unnecessarily to its power."

My article aimed only to express my belief that a vision of the ideal is necessary if we are to work our way through the host of social, ethical, technical, and economic changes which confront us. It is my conviction that physicians, drawing upon the strong traditions of their profession, and enlisting the support of leaders in the community, should seize the opportunity to direct the development of the future of medicine and medical institutions. That will take a shared vision, perhaps a degree of idealism that other more pragmatic realists would call naive.

It seemed to me that that kind of shared vision had led to the success of the public school movement. My comparison went no further; I intended to imply no analogy with the *form* of the public school system, which is in any case not a centralized system.

I do not understand Dr. Mark's question to me regarding "governmental control of Yale, Harvard, or Johns Hopkins." I would abhor government control of any university, including those which are state-owned, and cannot imagine a situation in which state acquisition of any of our great private institutions would be desirable.

My motive in writing the September "Reflections" was to urge physicians and others responsible for health policy to take the high road, opposing earnestly and with principle those who would make health into a business and medicine into a trade.

Robert U. Massey, M.D.
Farmington, CT

1. Mill JS: On Liberty (1859) The Philosophy of John Stuart Mill. New York: The Modern Library, pp 312-313, 1961.

HANDICAPPED PHYSICIANS IN PRACTICE

To the Editor: Dr. El-Mallakh's interesting survey of handicapped physicians in practice (Oct. '85 issue *Connecticut Medicine*) contains a false assumption, that pathology entails a "less rigorous work day" than other specialties. Our personal experiences, in completing Pathology residencies after years in Internal Medicine residency, differ sharply, as do those of the numerous Anatomic Pathology residents we have trained subsequent to clinical residency in Medicine, Otolaryngology, or Rotating Internship: the work day begins early and often runs into the late evening. Although Pathologists almost never have to sleep in the hospital, all come in at night on occasion, and most work every night and every weekend. Without exception, former clinical residents who undertake Pathology comment that the workload is comparable to or greater than what they had experienced in other fields.

Fortunately, his misconception does not invalidate Dr. El-Mallakh's work. We wish to set the record straight lest any credulous reader contemplate a shift to Pathology on false grounds.

Henry Schneiderman, M.D.
Assistant Professor of Medicine
Assistant Professor of Pathology

Ronald M. Maenza, M.D.
Program Director, Anatomic Pathology Residency
Associate Professor of Pathology
University of Connecticut Health Center, Farmington, CT

1. El-Mallakh RS. Survey of handicapped physicians in practice. Conn Med 49:643-644, 1985.

The above letter was referred to the authors of the article in question who offer the following reply:

To the Editor: I agree with Drs. Schneiderman and Maenza's objection to the terminology describing presumed physical exhertion of a pathologist. Different specialties possess differing physical restrictions, which may make a specific specialty more attractive given a certain handicap. It is the *ultimate* purpose of research such as this to reach behind a priori assumptions and determine the best way to advise newly handicapped physicians.

Rif S. El-Mallakh, M.D.
Department of Neurology
The University of Connecticut Health Center,
Farmington, CT

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FROM THE EXECUTIVE DIRECTOR'S OFFICE

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Government Relations

SUMMARY OF PROCEEDINGS
CSMS HOUSE OF DELEGATES–SEMI-ANNUAL MEETING
Ramada Inn, North Haven—November 20, 1985

Reports and Resolutions

The House of Delegates received reports from the President, the Council, the AMA delegation, the Executive Director, Connecticut Medical Political Action Committee (COMPAC) and from the Connecticut Medical Management, Inc. (CMMI). Resolutions were also received from the Council and individual members.

Principal Actions Taken

(a) **Report of the President,** William A. Whalen, M.D., Willimantic: The House VOTED to accept the report of the President, which included a report of his visits to the semi-annual meetings of the county associations at which he reported on the development of speakers' panels, professional liability crisis, health care systems, leadership conference and the possibility of ACSMS establishing an IPA/HMO.

(b) **Report of the Council,** Guy W. Van Syckle, M.D., Danbury: The House VOTED to accept the report of the Chairman of the Council, which reviewed the activities of the Council since the last meeting of the House of Delegates. (The complete text of this report of the Council is published elsewhere in this issue of *Connecticut Medicine.*) Special emphasis was placed on the Society's Professional Liability Program (CMIC), which now has enrolled more than 1600 members; Connecticut Peer Review Organization (CPRO); public education activities; the 1986 Budget; Labor Unions for Physicians and a Statewide IPA/HMO. Detailed information was distributed with the Report of the Council on Labor Unions and a Statewide IPA/HMO.

Edward A. Kamens, M.D., Fairfield, Medical Director of the Connecticut Peer Review Organization, reported on the activities and problems encountered in the operation of CPRO and that as of December 16, 1985 that office will be reviewing all hospital admissions for medicare patients in Connecticut.

(c) **Report of the Executive Director,** Mr. Timothy B. Norbeck, New Haven: The House VOTED to accept the report of the Executive Director which discussed the activities of the Society which included the legislative program, CMIC, public affairs program, professional liability, CME hospital accreditation program and other miscellaneous activities.

(d) **Report of the AMA Delegation,** Guy W. Van Syckle, M.D., Danbury: The House VOTED to accept the report of the AMA Delegation, which was prepared by Guy W. Van Syckle, M.D. The comprehensive report contained all of the principle actions taken at the 1985 Annual Meeting of the AMA House of Delegates. The report contained information on Tort Reform, DRG Program, Indemnity Payment System, Physician Supply and the National Relative Value Scale.

(e) **Connecticut Medical Political Action Committee (COMPAC),** Patrick Concannon, M.D., Middletown, Chairman of COMPAC: The House VOTED to accept, as information, the report of the Chairman of COMPAC which mentioned that 1985 was a record-breaking year and that over 500 physicians have joined COMPAC with more than 200 of these being Sustaining Members. He further reported that while the organization had more members than ever before, they were far from their goal and need greater participation in COMPAC from CSMS members.

(f) **Budget for 1986:** The House VOTED to approve the budget for 1986, as prepared and recommended by the Council and also VOTED to amend the dues increase of $75.00 recommended by the Council to a $100.00 dues increase.

The House VOTED to adopt the following resolutions:

Resolution on Statewide IPA/HMO

RESOLVED: That the Connecticut State Medical Society authorize an ad-hoc committee appointed by the Chairman of the Council to conduct a feasibility study on the advisability of the formation of a CSMS sponsored IPA, IPA/HMO, or HMO, and that the ad hoc committee report back to the Council and to the House of Delegates as soon as possible with a proposed business plan.

Resolutions from Ad Hoc Committee on Unified Membership

RESOLVED: That the House of Delegates request all county medical Associations to change their bylaws, if necessary, to require county/state unified membership

RESOLVED: That all county medical associations establish membership committees to work in liaison with CSMS and AMA to engender grass-roots unification activity.

RESOLVED: That Registration badges bear distinctive AMA and COMPAC ribbons at future CSMS meetings.

RESOLVED: That CSMS prepare literature citing the benefits of unified membership.

RESOLVED: That the CSMS leadership conferences be supported.

RESOLVED: That the Presidents' meetings be encouraged.

RESOLVED: That the CSMS delegation to AMA consider trying to get the AMA to grant the 10% dues discount to unified county medical associations and not just to unified states.

Resolutions on Smoking

(1) RESOLVED: That the Connecticut State Medical Society continue to work toward a tobacco free society and the elimination of passive smoke from the indoors.

(2) RESOLVED: That the Connecticut State Medical Society oppose any form of media advertising of tobacco products, and support legislation prohibiting such advertising in the State of Connecticut.

(3) RESOLVED: That the Connecticut State Medical Society prohibit use of tobacco in any form at all sessions of the Society, and to encourage county associations to do likewise.

Resolutions from CSMS Judicial Committee

RESOLVED: That the name of the "Judicial Committee" of CSMS be changed to the Committee on Ethical and Judicial Affairs, and be it further

RESOLVED: That the charge of the present "Judicial Committee" be amended to read as follows:

(Judicial) Committee on Ethical and Judicial Affairs

a. Composition. The (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS shall consist of twelve members of the Society. Each member must have been a member of The Society for ten years and have served as an officer of The Society or of a component County Association: No member shall serve for more than two consecutive terms. The Council shall annually nominate to the House of Delegates one member of the (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS from each of two component County Associations, in quadrennial rotation, and one member-at-large, each to serve a four year term. Biennially, the Council shall also nominate a chairman of the (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS for a term of two years. No chairman shall serve more than two terms in succession.

b. (1) Functions. The (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS shall be the Board of Censors of The Society. All questions concerning CODES OF ETHICS, MATTERS OF BIOETHICS, AND medical ethics brought before the House of Delegates or a general meeting shall be referred to the (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS without discussion. It shall hear and decide all questions (of discipline) affecting the conduct of members of component Associations on which an appeal is taken, and its decision in all such matters shall be final, except as hereinafter provided. The Committee may study and render an opinion when indicated on any question referred to it from the House of Delegates, the Council, from any other responsible source or on its own iniative involving the rights, standing, or obligations of members in relation to other members or to a component Association or to The Society or any subdivision thereof, or on any question concerning BIOETHICS, CODES OF ETHICS, medical ethics or affecting the good name of the profession, or on any litigation arising out of a physician's practice. The (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS shall serve as a board of review for ALL cases (of claimed malpractice) OF ANY NATURE referred to it by (the committee on medical ethics and deportment of) any component County Association.

(2) The (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS shall have the power to interpret the Charter, Bylaws and Rules of The Society and the component County Associations; to decide any dispute or questions between The Society and component County Associations, or between County Associations.

(3) Investigating Subcommittee: The (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS acting on its own motion or on request from any responsible source, may request the Council to appoint a subcommittee to investigate and report on any complaint or condition in the State of greater than local concern affecting the profession as a whole. If the subcommittee finds that there is probable cause for action, it shall so state. The Council shall, in turn, submit the report to the (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS. If the (Judicial) Committee agrees that there is need for action, it shall first request the County Medical Association having jurisdiction to take appropriate action and to submit a report of the facts found and the action

taken. The (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS may act in its appellate function as to any action taken by the County Association in the matter.

(4) The (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS shall be, or shall represent The Society on, a Panel for Physician-Hospital Mediation. The chairman may appoint an ad hoc subcommittee of three members, who shall be impartial as to subject matter, persons involved and other prejudicial factors, to assist in resolving disagreements involving members of The Society when those procedures recommended by the Joint Commission on Accreditation of Hospitals have failed.

(5) The (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS shall render a report to each annual meeting of the House of Delegates, including its actions, opinions, and recommendations and shall make such interim reports as it desires or as are requested by the House of Delegates. Such reports shall be available to members of The Society.

c. (1) Jurisdiction. The judicial power of The Society shall be vested in the (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS, with jurisdiction over all members of The Society, acting within its function. Its decisions shall be binding on the parties concerned and specific problem considered, but shall be considered only as a presumption of The Society, binding on all members, only when endorsed by the House of Delegates and published to the membership. The (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS may use its judgment whether or not to request such endorsement from the House of Delegates for the purpose of establishing such a principle.

(2) The (disciplinary) findings and acts of the (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS whether in exercise of its original jurisdiction or its jurisdiction in appeals from component associations, shall be subject to such rights of appeal to the AMA as may from time to time exist under AMA rules and procedures. Execution of the decision or action of the (Judicial) Committee ON ETHICAL AND JUDICIAL AFFAIRS shall be automatically stayed during such period as may be authorized for any such appeal to the AMA and also, unless the (Judicial) Committee otherwise provides, during the pendency and disposition of such appeal.

d. Procedure. A majority of the members shall constitute a quorum. The Committee shall meet at (least three times each year and may hold such additional meetings as are needed) THE CALL OF THE CHAIRMAN. The Council shall fill any vacancy occurring between meetings of the House of Delegates The Committee, in any ethical OR BIOETHICAL problem which, in its judgment, transcends medical ethics, may invite discussants and participants, lay as well as medical.

NOTE: Parentheses mean deletion. Capitals mean addition.

Labor Unions for Physicians

A 44 page packet of information drawn from AMA sources, legal opinions rendered to CSMS and New Haven County, and from the union itself was distributed to all members of the House of Delegates with their Handbook for the meeting. Following review of the material and discussion, the House of Delegates VOTED to provide a brief summary of this information to all CSMS members.

AWARDS

CSMS Past Service Awards to Officers and County Councilors

OFFICERS

John J. Mendillo, M.D., Branford	
Treasurer	1979-1985
Daniel W. Doctor, M.D., Westport	
Councilor-at-Large	1984-1985

COUNTY COUNCILORS

Fairfield County

James P. Orphanos, M.D., Greenwich	
Associate Councilor	1981-1982
Councilor	1982-1985

Hartford County

Norman Alisberg, M.D., West Hartford	
Associate Councilor	1983-1985

Middlesex County

Patrick R. Concannon, M.D., Middletown	
Councilor	1982-1985

New Haven County

Robert R. McDonnell, M.D., New Haven	
Associate Councilor	1980-1984
Councilor	1984-1985

Tolland County

Michael R. Sharon, M.D., Rockville	
Associate Councilor	1982-1985

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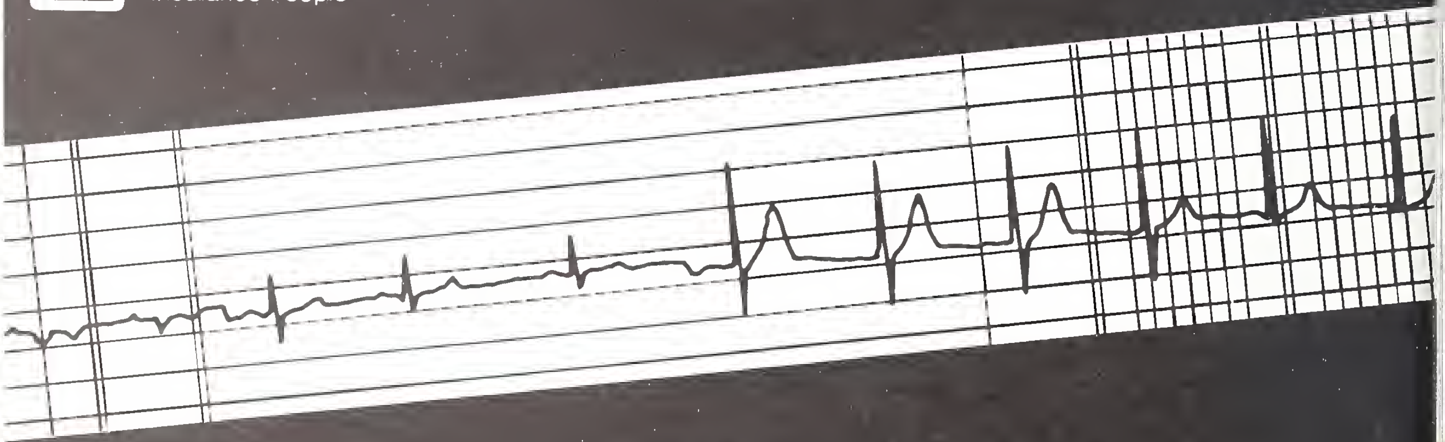

SEMI-ANNUAL REPORTS TO THE HOUSE OF DELEGATES OF THE CONNECTICUT STATE MEDICAL SOCIETY

November 20, 1985

Report of the Council

GUY W. VAN SYCKLE, M.D., CHAIRMAN

The Council has met three times since the Annual Meeting of the House of Delegates held May 8, 1985. All members of the House have received detailed copies of the minutes of each meeting (minutes of 10/24/85 meeting included with this Handbook). Therefore, this report is limited to those matters which are felt to merit special emphasis. At the conclusion of the report, as appendixes, there are published items of business which are transmitted by the Council to the House accompanied by recommendations of the Council. The number given to each of the appendixes is identical with the number of the related section of this report. Since this report was written prior to the October 24 Council meeting, these minutes constitute an addendum to the report of the Chairman of the Council.

1. PROFESSIONAL LIABILITY PROGRAM

The Connecticut Medical Insurance Company presently reports that it insures approximately sixteen hundred Connecticut physicians as compared to some nine hundred physicians last year. Our company lists assets of approximately $13,000,000 at present with a projected estimate of $30,000,000 in assets at this time next year. CMIC instituted a premium increase of 17.6% and reported that it had completed a computer hook-up with the Medical Inter-Insurance Exchange which is a captive company of the Medical Society of New Jersey. CNA and St. Paul continues to market liability insurance programs for the physicians in the State. There is a growing trend for physicians to switch to claims made from occurence type policies. Insurance trends in the industry would indicate that there is an increasing chance that only claims made type programs will be available in the near future.

The AMA sponsored a teleconference on professional liability on June 3, 1985. CSMS participated through arrangement with Yale. The AMA Task Force on Professional Liability and Insurance has developed a seventeen point action plan for public education, accompanying legislative reform, coordinated defense and quality review.

R. Leonard Kemler, M.D., Hartford, was named to be the Society's representative on the Task Force on Health Care Liability Insurance. This task force was an outcome of the last legislative session. Joseph Sadowski, M.D., Hartford, was elected Alternate Delegate.

2. CPRO

Dr. Edward Kamens has reported regularly regarding CPRO activities. To date, the organization has made over 60,000 reviews and that, at present, preadmission certification is required in one-third of the hospitals in the State.

The Society, in response to a request of the CPRO nominating committee, submitted the following names: Doctors Daniel Doctor, Mehdi Eslami, George Bonner and Isadore Friedberg.

3. PUBLIC EDUCATION ACTIVITIES

The President, William A. Whalen and Executive Director, Timothy Norbeck, have appeared on public radio discussing medical malpractice insurance crisis. Mr. Norbeck has continued his policy of speaking before groups of interested lay people, especially the AARP and League of Women Voters.

4. LEGAL ACTIVITIES

The Society is presently involved in two actions with legal ramifications. We are presently objecting to certain regulations of the Commission on Hospital and Health Care regarding the reporting of extensive patient and physician data by general hospitals. CSMS is presently supporting legal action to block these requests.

The podiatrists continue to claim "the ankle as part of the foot" and therefore within the scope of podiatry practice in Connecticut. We are presently engaged in activities to restrict this extension of their practice.

Finally, the Society is actively investigating the potential of countersuit against unsuccessful plaintiffs in a malpractice action. An ad hoc committee was appointed to:

1. Establish guidelines regarding selection of countersuit cases.
2. Determine ways to finance such countersuits.
3. Establish a format to evaluate requests for financial aid that arise from the membership.

The members of the committee are: Doctors William Schear, Chairman, Larry Coletti, Jerome K. Freedman, W. Raymond James, Joseph S. Sadowski, Bernard F. Sheehan and Annemarie Welch.

4. LEGISLATION
   Chairman Jerome Bobruff, M.D., has reported regularly on the activities of his committee. During the last session, CSMS defended the present statute of limitation against efforts to extend the time limits for suits. Seat belt law and living will legislation supported by the Society was passed. A collateral source law which has been vigorously sought by CSMS over the years, was finally passed. The Society will be monitoring closely the activities of the newly established State Study Committee on Professional Liability.

5. 1986 BUDGET
   Attached to this report as Appendix Item No. 5 is the Budget for 1986. The budget has been reviewed line by line by the Council and the Council voted to approve the budget and transmit it to the House of Delegates with the Council's recommendation that the dues structure of $250.00 and budget be approved by the House of Delegates.

6. CONCLUSION
   As indicated in the opening paragraph, only matters that are thought to be of major importance were included in this report. The members of the House are urged to review the minutes of the meetings held since the Annual Meeting of the House of Delegates. As Chairman of the Council, I shall be happy to answer any questions about any other items recorded in the minutes of the Council. At this time, the Chairman would like to express his appreciation and thanks to all members of the Council and staff whose cooperation and assistance have been invaluable.

N.B.: *Actions taken on the items in this report appear in "Summary of Proceedings of the House of Delegates" under "From the Executive Director's Office" in this issue of* Connecticut Medicine.

Report of the Executive Director

TIMOTHY B. NORBECK

It has been six hectic and chaotic but also successful months since I last had the opportunity to address the House of Delegates. Through a combination of physician involvement, candidate support, lobbyist activity and staff support, we achieved a remarkable string of legislative victories. We successfully defended Connecticut's favorable Statute of Limitations and were able to eliminate the collateral source rule. A task force to study the problem of health care liability insurance was established and will report in February to the legislature. Governor O'Neill also set up a task force to study liability insurance availability. We have high hopes of attaining further tort reform through these task forces.

COMPAC, the Connecticut Medical Political Action Committee, has never been in better shape. We have well over 500 members, and more than 40% of them are sustaining members. This is quite an improvement over past years, but it is not enough for an organization which exceeds a membership of 5,000. The Connecticut Trial Lawyers Association is deeply perturbed by our victories and has quadrupled its expenditures for lobbyists and is building a massive war chest to thwart our efforts for further tort reform.

Our first Leadership Conference, held on September 7, was an unqualified success. On a scale of one to ten, the registrants gave the overall conference a nine.

A little less than two months ago marked the first aniversary of the Connecticut Medical Insurance Company, your physician-owned professional liability insurance company established by the Connecticut State Medical Society. CMIC now has 1,641 policyholders, has enjoyed a steady rate of growth, and looks to the future with confidence.

In support of voluntary quality continuing medical education, CSMS has, over the past five months, eliminated the backlog of overdue CME accreditations, with 17 hospitals site-visited by CSMS survey teams and is among the very first state medical societies to have undergone ACCME's (Accreditation Council on Continuing Medical Education) new national recognition process.

A rejuvenated Public Affairs program is bearing fruit with more and more of our weekly news releases receiving coverage in the media. In addition, the first set of posters sent out to CSMS physicians has been well received. An increasing number of presentions have been made to Rotary Clubs, Lions Clubs and meetings of the AARP and League of Women Voters.

The CSMS Sports Medicine Committee has had great success in publishing its quarterly newsletters and the response to its sport medicine seminars has been gratifying.

TIMOTHY B. NORBECK, Executive Director of the Connecticut State Medical Society.

There is one other matter alluded to earlier on which I would like to spend a few more minutes.

In all likelihood, whatever tort reform is to be attained in this next session of the legislature will come through the health care liability task force. Our delegate, Dr. Leonard Kemler from Hartford, is one of 15 members of that body. CSMS Immediate Past President, Dr. Joseph Sadowski, is our alternate delegate.

While we would like to think that the government in its wisdom will take the right steps and pass legislation to alleviate this crisis, we cannot take such a thing for granted.

One of my favorite stories about the realities of how government operates took place in the early sixties when John F. Kennedy was President of the United States. In 1961, Senator Bob Kerr of Oklahoma, a very wealthy and powerful man who was also Chairman of the SFC, asked to see the President. He was upset that Kennedy was going to veto a recently passed bill by Congress which would bar the importation of zinc. Zinc manufacturers in Oklahoma felt strongly about the legislation and pressured Kerr to see that it passed.

Kennedy received Kerr in the Oval Office with his aides, Mike Feldman and Ted Sorensen and said, "Bob, I'm sorry but it's a bad bill."

"Mr. President, could I speak to you privately? There are a few things you may not understand about the legislation."

"Sure, Bob, but it's not going to change my mind. I've been briefed pretty thoroughly by Ted and Mike."

When Sorensen and Feldman left the room, Kerr drawled, "Mr. President, you are my leader and I will abide by your decision."

"Bob, I appreciate that."

"But, Mr. President, my people were pretty mad when Ike vetoed that same bill, and I will have to go back to Oklahoma and spend full-time defending your action."

"I really appreciate that."

"But, Mr. President, you must understand that if I'm away in Oklahoma, your tax bill, which lies in the Finance Committee which I chair, will never come to the floor."

"Bob, this is the first time anyone really explained the zinc bill to me—I'll sign it."

Actually I feel confident that our Connecticut General Assembly *will* do the right thing and pass needed tort reform as it did in the past session. But all of us in this room and your physician colleagues throughout the length and breadth of Connecticut must recognize that there is an acute need for us to spread the word on this crisis to the public. That need is acute because there are a number of trial lawyers who claim that there is *no* crisis—that *if* there is a malpractice insurance crisis, it is due to malpractice.

The Trial Lawyer who sits on the Connecticut legislative task force referred to earlier, distributed to all members of that body an article he had written for the Connecticut Law Tribune. In his article he talks about the medical conspiracy of silence and of the need to publicize all of the incidents of malpractice so that, as he put it, the incidence of medical malpractice would drop and the quality of medical care would improve.

We know that malpractice does exist, but we *also* know that so many alleged victims of malpractice have improperly equated injury with malpractice. The facts indicate that *most* of the suits are filed against the best-trained, highly-skilled physicians at the peak of their careers.

If there isn't a medical malpractice insurance crisis, why have Connecticut physicians' premiums doubled over the past three years and quadrupled in the past six—a trend which, unless arrested soon, could grow to the New York and Florida levels of $100,000. If not a crisis, why is reinsurance so difficult to purchase even at inflated prices? Lloyds of London, one of the biggest and best known reinsurers in the world, shocked the insurance industry earlier in the year when it announced that it lost money for the first time in its 300 year history. Lloyds blames liability litigation in the U.S. for the crisis market.

Those of you involved to some extent in your communities are probably aware of the massive crisis encountered by those municipalities in obtaining liability insurance. *Why the problem?*

Insurance analysts claim that the *primary reason* for escalating premiums lies with the courts, which are handing out *increasingly large settlements* in cases against municipalities. I would ask the physicians in the audience, "Does that sound familiar?"

Experts say that people sue municipalities because they believe towns and cities have *"deep pockets"—again—* "Does that sound familiar?"

In the past six years, the rate of malpractice claims has doubled. *This despite the fact that we have the finest medical care system ever devised* with the best trained physicians and the latest and best technology. The record speaks for itself. *People see who were destined to be blind. People hear who were deaf. People walk after being confined to bed or wheelchair. People live constructive lives who once were considered hopelessly doomed.* More than *one-half* of all the diagnostic and therapeutic tools used by doctors today did not exist anywhere in the world just ten years ago.

So why all the litigation? According to U.S.A. Today, the answer is that "we live in a society that loves to sue. Citizens sue the government. Wives sue their husbands. Some children even sue their parents. So why not sue the physician, too?

In an age of high-tech medicine, patients have high expectations—sometimes too high. If the medical miracle they expect doesn't work out, they want revenge."

The 1973 Presidential Commission on Malpractice explained the high number of suits this way:

"*The press and broadcasting media fostered greater public interest in medicine and particularly in its miracles leading the public to develop many unrealistic expectations about medicine's capabilities.* Many Americans regard good health as though it were a *commodity*, something that the doctor *can dispense at will*. But good health *is not* a purchasable commodity. It is a matter *first* of *heredity* and, *above all*, a matter of *personal responsibility, choice* and *self-governance*. unfortunately, the failure to achieve ideal health has caused great disappointment with the results of treatment on the part of *some* patients and they have turned with greater and greater frequency to the lawsuit as a means of resolving their disappointment."

Newton Minow, a lawyer and former head of the FCC, said recently that when *he* was in law school, students were taught to ask "*Who is at fault*?" When his daughter went to Law School years later, *she* was taught that the *real* question was: "*Who is best able to pay*?" Therein lies the root of the malpractice crisis.

Obviously much more can be said about this problem, and we will go into greater depth on it at the speech seminar scheduled for Saturday morning alluded to by Dr. Whalen.

The question is not what *can* we do but what *must* we do. We must mobilize like never before and spread the word to everyone who will listen to us. Legislative strategies will be discussed with the county medical associations and needed statistics will be shared with all physicians. We will need your help in conveying this information to the public, and we in turn offer our help to you on whatever plane or scale you require.

The climate is right and we are on the right side of this issue, but we must not take anything for granted. The Connecticut Trial Lawyers Association is prepared to spend whatever time and funds are necessary to achieve its purpose—that is, to overturn the legislation passed this past year and to defeat our efforts for more tort reform in 1986.

One other important comment should be added. We want to avoid the struggle for tort reform becoming a doctor versus lawyer fight. Our position will not be inflammatory towards lawyers and we will make our case for tort reform using logic and facts. Hopefully the effort to attain our goals can be achieved without degenerating into a downright battle between the professions.

We plan to keep CSMS member physicians and our county medical associations fully apprised of legislative developments. A newsletter is being prepared now for mailing in early December.

Some thirty-four years ago, AFL-CIO President George Meany had the following to say about union efforts and I know of no better words to describe our present situation: "We make progress by fighting for progress. We will only retain the gains we have made by constant vigilance and by a demonstrated willingness to fight again. So when we look back at our gains, let us do so not for the purpose of indulging ourselves in the luxury of a feeling of satisfaction or complacency but for the knowledge and inspiration needed to carry on in the direction of even a better day."

Report of Connecticut Medical Management, Inc. (CMMI)

JEROME K. FREEDMAN, M.D., PRESIDENT

Connecticut Medical Management, Inc. is the wholly owned subsidiary of the Connecticut State Medical Society. Its purposes are to manage the Connecticut Medical Insurance Company, to implement the policies of the Board of Trustees of that company and to represent the interests of the CSMS in CMIC. Currently the management function is in the capable hands of our professional advisers and managers, American Insurance Services.

Our second year of existence is just beginning, one thousand policy-holders have become one thousand six hundred or so and CMIC is either the largest or one of the largest underwriters of medical malpractice insurance in Connecticut, a not too bad result after so short an existence. CMMI's responsibilities grow accordingly. Last month we had a ledger value of thirteen millions of dollars and at the end of our next policy year we will in my estimation exceed thirty million. You know that each of us takes this responsibility very gravely, indeed.

During it's first year, the CMMI Board spent hundreds of hours individually and together in rather formal education. We needed to be able to understand such things as balance sheets, statutory insurance reports, corporate accounting, investment management, the bond market, computer selection, reinsurance, marketing, personnel selection and day to day management functions. Each and every member of the CMMI Board has been dedicated and diligent. I wish to express my personal appreciation to Doctors James, Ahamed, Dowling, Sadowski, Orphanos, Doctor, Eslami and to Mr. Norbeck. Each has been devoted and in no way could any of them be compensated adequately for what they each have done this year for the physicians and the patients of Connecticut.

As I said above, we are either the largest or one of two largest underwriters of medical malpractice insurance in the state. An efficient office is functioning, staffed with capable people. Underwriting, Claims and Risk Management programs have been formulated and implemented. Fiscal management is done with the help of AIS, DeLoitte, Haskins and Sells, Wiggin and Dana and Brown Brothers, Harriman. I would describe it as responsibile, conservative and prudent. The investment program selected is suitable for a new insurance company in a very risky and unpredictable line of business. A computer software system has been purchased from the Medical Insurance Exchange of New Jersey and our terminals are hooked up to their computer. The system is functional and is working well according to staff. Drs. Dowling, Sadowski and I have visited several of our major underwriters in London and have been subjected to unbelievably intense scrutiny by them. Thanks as much or more to our capable AIS advisers and their established reputation in London as to any great genius on our parts, we passed the exam with flying colors. That is, we were successful compared to other companies coming to the reinsurance market, given the poor state of the world property and casualty insurance market in general and medical malpractice insurance in particular. We were able to offer relatively reasonable premiums for our second year, calculated we think, very conservatively and prudently.

Certainly, there have been problems during this first year. Reinsurance is a very unsettled and unreliable business. The future of occurrence policies is in doubt. The size of judgments increases and the philosophy seems to be that all physicians who lose cases are incompetent, as I saw in the *New York Times* again this morning. Maloccurrence is a foreign concept to the media, apparently. We have help from the generally poor property and casualty market and there is no more outraged politician than the one who finds the premiums for his own government's liability insurance have gone up. Not to gloat, but it is not entirely bad when towns in this state have trouble getting insurance. It begins to convince some that we are not fabricating the problem.

We are not excused from very careful management, including thoughtful underwriting, careful and intelligent claims handling and conservative money handling. Do not think that an application for it in any way guarantees insurability or reinsurability. And this year we surmounted hitches in operations and management. These are expected when dedicated and strong willed physicians work together. So far the two Boards of Trustees have related to each other well. We of CMMI are well begun on the way to being educated overseers of the management staff of a medical malpractice insurance company. There is much more to learn and the AIS staff are dedicated and excellent teachers. So we will learn, I promise you.

I believe this report gives the Council and the House of Delegates enough of the facts and the flavor of the first year of CMMI operations for you to draw conclusions about our activities. I believe we are developing management skills and knowledge and are maintaining CSMS influence and input into the insurance company CSMS began last year with so much effort, time and expense. I believe that we have up to now met the requirements you placed upon us last year. We intend to continue to do this into the indefinite future as the company grows.

Report of the Annual Meeting of the AMA House of Delegates

Chicago, June 16-20, 1985

The AMA House of Delegates met in Chicago on June 16–20, 1985. There were 375 delegates seated in the House. 296 represented state medical associations, 66 delegates represented national medical specialty societies and 9 section and service delegates represented medical students, medical schools, resident physicians, hospital medical staffs, Army, Navy, Air Force, USPHS and the Veterans' Administration. One new specialty society was granted a voting seat of the House at this meeting: The American Academy of Otolaryngic Allergy.

AMA President, Joseph F. Boyle, M.D., in his presidential address cited a number of opportunities that the profession has to renew its accountability for standards in practice, to recognize and uphold its responsibilities and to restore the public's confidence in medicine. In his speech, he particularly stressed the elimination of inappropriate utilization and excessive charges where these exist and, secondly, to exercise increased professional discipline through effective risk management and peer review.

Frustration was the theme and anger the by-word as the delegates worked through their agenda during this meeting. The sources of the frustration and anger were in response to DRGs with shrinking federal reimbursements, the growing number of limited license practitioners, the perceived glut of physicians, increasing competition and the continuing threat with actual loss of physician autonomy in caring for patients. A continuing source of frustration and anger, as at previous meetings, was the deepening crisis in availability and affordability of professional liability insurance.

The following is a brief summary of the most pertinent discussions and activities taken by the AMA House of Delegates:

AMA Proposed Federal Legislation for Tort Reform

Under the AMA's program, states would have to enact five major legislative reforms to alleviate the crisis in professional liability and receive incentive grants from the federal government. The five reforms are:

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- •Periodic payments for future damages exceeding $100,000
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- •Placement of a $250,000 cap on non-economic damages.
- •Restriction of the contingency fees of attorneys representing medical injury claimants.
- •Implementation of a five part program of peer review discipline and risk management.

Additional house actions regarding professional liability were:

- •The AMA Liability Task Force was directed to use all appropriate means to inform the public that the crisis and its potential harm to the public and ask for the development of an alternate method to the court/jury system whereby parties who had been injured through negligence receive just renumeration without adversely affecting the entire health delivery systems.
- •The House directed the AMA to expedite the preparation of an expanded and more specific response to the American Trial Lawyers Association's contentions regarding the current situation in professional liability.
- •Adopted a resolution urging state medical societies to develop good samaritan laws to protect qualified medical personnel in those states lacking such safeguards.
- •Referred to the Board were resolutions urging that the AMA develop a coalition of organizations supporting broad tort reform; that the AMA study the feasibility of sponsoring a national medical risk management commission; and that the AMA seek remedies to liabilities arising out of improper review decisions regarding outpatient and inpatient medical care.

Federal DRG Program

The House approved a position statement expressing AMA's continued reservations about the overall impact of the diagnostic related group systems on patient well being and the capabilities of hospitals to continue to provide quality care under that system.

Indemnity Payment System

The House voted to reaffirm its support for the validity of the indemnity payment system as one of the pluralistic approaches to payment methods. It also called on the Association to implement the idemnity payment system as a preferred policy at the national level.

Physician Supply

The House called on the AMA to recognize the concerns of physicians, the public and various governmental bodies regarding the issue of physician supply and maldistribution. It recommended the formation of a task force to study the problem by evaluating the effects of physician supply and distribution on the quality and cost of medical care. It also asked state medical societies to study their own local situations in conjunction with state governments.

National Relative Value Scale

The House received a progress report on the AMA's efforts to secure a grant from HCFA to develop a resource cost based relative value scale for physicians' services. The report pointed out that a relative value scale is not a fee schedule. The AMA will continue its strong opposition to the implementation of any mandatory fee schedule.

AMA Finances

The issue of AMA finances and the need for additional dues revenues was a prime issue before the House. After the anticipated vigorous debate, the AMA House of Delegates adopted a $45.00 increase in the regular membership dues to $375.00 effective in 1986. The House carefully reviewed the finances of the AMA and the important programs and activities conducted by the AMA on behalf of physicians and their patients. The AMA had been operating with a minimal excess of revenue over expenses of approximately 1%. In 1985 this margin was seriously eroded. In addition, at the same time, the AMA was undertaking new important initiative including aggressive implementation of activities that address the professional liability crisis; the decision to implement unified membership and a public information campaign that will heighten public awareness about changes in the medical delivery systems. The $45.00 dues increase will generate enough revenue to cover expected inflation in 1986, to resume some of the programs that were delayed, reduced or eliminated in 1985 and to conduct programs that will continue the leadership demanded by the membership.

AMA Judicial Council

The AMA's Judicial Council will become the Council on Ethical and Judicial Affairs and will increase to seven members from five in recognition of the increasing volume of responsibilities undertaken by the Council. The Council noted that in its report, it was launching a new program to highlight the role of the AMA in setting and maintaining ethical standards of the medical profession. It is planned that there would be increase in the use of the Council's panel of consultants on bio-ethical issues, expanded coverage of Council reports and statements in AMA publications together with development of a rapid response mechanism for inquiries regarding ehtical issues. A conference on ethical issues is planned in 1986.

AMA President

Harrison L. Rogers, Jr., M.D., an Atlanta general surgeon became the 140th President of the American Medical Association in inaugural ceremonies on June 19th. He called on physicians to demonstrate leadership in medical care in the present climate of increasing government regulation, escalating professional liability crisis and eroding public image of physicians. He stated that physicians must assert their presence in "a contest of leaderships" for control of US health care.

Hospital Medical Staff Section

The Hospital Medical Staff Section was extremely active prior to the start of the House of Delegates meeting. Their activities resulted in ten resolutions being sent on to the House. Of these ten resolutions, only one was rejected. The others were either referred to the Board or accepted by the House. The primary concerns, as on previous meetings, the HMS debate centered on conflicts between the hospital Board of Trustees and medical staff. It continues to attempt to define the relationship between the two groups as an equal one in which the Board of Trustees has the fiduciary responsibility of operating the facility and the staff has the ultimate responsibility of delivering high quality medical care.

The AMA meetings continue to be educational and relevant. All members of the Association are urged to attend if possible or at least express their views and concerns to members of the Delegation.

FOR THE CONNECTICUT AMA DELEGATION: Guy W. Van Syckle, M.D., Chairman, Frank K. Abbot, M.D., Edward A. Kamens, M.D., Stewart J. Petrie, M.D., Andrew J. Canzonetti, M.D., Jerome K. Freedman, M.D., Isadore H. Friedberg, M.D., W. Raymond James, M.D., William A. Whalen, M.D., Joseph C. Czarsty, M.D.

CAVEAT: MEDICAL EXEMPTIONS UNDER THE CONNECTICUT SEAT BELT USAGE LAW

This is a summary of a statement endorsed by the Council of the Connecticut State Medical Society on 18 December 1985. The full statement was prepared by the Connecticut Safety Belt Coalition and has also been endorsed by the Connecticut Academy of Family Practice and the Connecticut Chapter of the American Academy of Pediatrics. More detailed guidelines for medical seat belt exemptions will be published in February's *Connecticut Medicine.*

The physicians of Connecticut have strongly supported the use of safety belts for many years, recognizing the fact that the mortality and morbidity incurred in motor vehicle crashes by unrestrained drivers and passengers are greater than by those properly restrained. Two decades of real world experience have proven that belts prevent or mitigage serious or fatal injuries by about 50%.

The Connecticut Safety Belt Law provides that anyone with a physical disability or impairment which could prevent belt use is exempt if he obtains a physician's written statement on the nature and extent of the condition and the reasons for the inability to wear a belt. The statement must be carried by the person or in the vehicle when it is being operated. Persons with "handicap" plates do not automatically qualify for the exemption.

WARNING: PHYSICIAN MAY BE LIABLE FOR SUBSEQUENT INJURY

A physician granting a medical exemption may be held personally responsible for his action and should be prepared to defend the medical exemption in court. It is conceivable that physicians granting exemptions may be sued by unrestrained patients subsequently injured in a motor vehicle crash. For this reason, physicians are advised to keep a record of any medical exemption granted and the reason for it, the date it was granted and its expiration date if any.

Experience in countries where belt use is required has shown that less than 1% of all motor vehicle related injuries are caused by the belt per se, predominantly under conditions when an unrestrained occupant would be much more seriously injured.

The Connecticut Safety Belt Coalition Recommends that:

- A Medical exemption should be granted only for a sound medical reason and never routinely. The safety belt law provides no categorical, specific or routine medical grounds for granting a medical exemption. Each case should be decided on its own merit.
- If a medical exemption is granted, a record should be kept by the physician of the medical reason given by the patient for the exemption, the documentation of the basis for which the medical exemption was granted, the date it was granted and the expiration date if any.
- For temporary conditions, a medical exemption should be granted for periods of no more than 6 months, and renewed as necessary. For permanent conditions, a medical exemption should be granted for no more than 4 years and renewed as necessary.

REQUIREMENTS OF THE CONNECTICUT SAFETY BELT USAGE LAW:

A medical exemption may be granted only by a licensed physician.

A certification of exemption for medical reasons must be issued on the physician's prescription pad or letterhead.

The patient's name, date of birth and address, the date of issuance of the exemption, a clear statement of medical exemption from belt use and the doctor's signature must appear on the certification.

Questions about the law, exemptions from the law and adaptation of existing seat belt systems should be directed to the Connecticut Safety Belt Coalition, 900 Asylum Avenue, Hartford, CT 06105, Tel 724-5945.

IN MEMORIAM

AMATO, PETER R., Tufts Medical School, 1961. Dr. Amato was a gastroenterologist in the Hartford County area since 1969. He was chief of gastroenterology and senior attending physician at St. Francis Hospital. Also, he was associate clinical professor at the University of Connecticut Medical School and a consultant at the Veterans Administration Medical Center in Newington and the state Veterans Home and Hospital in Rocky Hill. Dr. Amato was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died October 18, 1985 at the age of 49.

ANDRUS, OLIVER B., New York University School of Medicine, 1932. Dr. Andrus was a surgeon in the New Haven County area since 1932. He was a member of the medical staff of Milford Hospital and served as chief of staff from 1959 to 1962 and he was also a member of the courtesy staff of Bridgeport Hospital. Dr. Andrus was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died October 31, 1985 at the age of 82.

CUSHMAN, GEORGE L., Tufts Medical School, 1943. Dr. Cushman was a general practitioner in the Litchfield County area since 1948. He was appointed school physician for the town of Woodbury that year, and several years later he was appointed health director, a position which he held until January of 1985. Dr. Cushman was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died September 17, 1985 at the age of 67.

FLEISHER, PHILIP, University of Western Ontario, 1944. Dr. Fleisher was an urologist in the Fairfield County area since 1944. He was chief of urology at Park City Hospital, Bridgeport. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died November 30, 1985 at the age of 65.

GALEN, JACK H., Long Island College, 1942. Dr. Galen was a family practitioner in the New Haven County area since 1946. He was an associate in medicine at Griffin Hospital, Derby. In 1964, he was president of the New Haven County Medical Association. Dr. Galen was also a member of the Connecticut State Medical Society and the American Medical Association; died November 18, 1985 at the age of 68.

GRISWOLD, MAUDE T., Tufts Medical School, 1905. Dr. Griswold was a general practitioner in the Litchfield County area since 1905. She was school physician at the Harwinton Consolidated School for 25 years and also served as the town's health officer and was on the staff of Charlotte Hungerford Hospital. Dr. Griswold was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died October 25, 1985 at the age of 104.

HARRIS, BENEDICT R., Yale University School of Medicine, 1922. Dr. Harris was an internist in the New Haven County area since 1923. He was consulting at Yale-New Haven Hospital, the Hospital of St. Raphael and Griffin Hospital. Dr. Harris was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died November 3, 1985 at the age of 86.

KAPLOWE, JOSEPH L., New York University School of Medicine, 1930. Dr. Kaplowe was a general practitioner in the New Haven County area since 1931. He was founder of Health Dynamics and was a commissioner and president of the state Board of Homeopathy. Dr. Kaplowe was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died October 2, 1985 at the age of 82.

LOGAN, WILLIAM J., Yale University School of Medicine, 1925. Dr. Logan was a surgeon in the New Haven County area since 1926. He was the school physician for Albertus Magnus College and staff physician at the Hospital of St. Raphael and the former Highland Heights. Dr. Logan was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died November 15, 1985 at the age of 85.

MYLON, ERNST, Berlin University, 1921. Dr. Mylon was an internist in the New Haven County area since 1943. He was associated with Yale in the fields of medicine and biochemistry. Dr. Mylon was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died October 15, 1985 at the age of 90.

NOROOZ, HEYADAT, Pahlavi University School of Medicine, 1964. Dr. Norooz was an obstetrician in the Fairfield County area since 1975. He was associated with Bridgeport Hospital. Dr. Norooz was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died October 19, 1985 at the age of 45.

SPONZO, JAMES J., Tufts Medical School, 1938. Dr. Sponzo was a general practitioner in the Hartford County area since 1939. He was clinical associate professor at St. Francis Hospital, Hartford. Dr. Sponzo was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died November 21, 1985 at the age of 63.

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MANUSCRIPTS should be submitted to the Editor, J. Alfred Fabro, M.D., *Connecticut Medicine,* 160 St. Ronan St., New Haven, CT. 06511. Manuscripts are received with the explicit understanding that they are not simultaneously under consideration by any other publication.

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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

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FAMILY PRACTICE

Oct. '85. Age 39. FLEX. AB cert. MBBS, London University, Guy's Hospital; Int., Guy's Hospital, London and Farnborough Hospital, Kent, UK; Res., University Hospital, SUNY, Stony Brook, NY. Preference is to practice solo or with a group in a medium-sized shoreline community. Write, Patrick L. Neustatter, MBBS, 3216 Denton Dr., Merrick, NY 11566.

FAMILY PRACTICE—Continued

Available within 60 days notice. Age 33. Presently in practice. Nat'l bds. AB cert. MD, Int. and Res., Queen's University, Kingston, Ontario, Canada. Prefers a group practice with no obstetrics in a medium-sized community. Write, Lew H. Valliant, M.D., 115 Mountain View Dr., Elkins, WV 26241.

Sept. '86. Age 38. Nat'l bds. AB elig. MD, Temple University, Philadelphia, PA; Int. and Res., York Hospital, York, PA. Desires group type practice in a small to medium-sized community. Write, John (Sean) L. Barrett, M.D., 226 W. Jackson St., York, PA 17403.

Mature Family physician, B/C, with many years of experience including industrial medicine, seeks full time work in a medical facility in Southern Connecticut. Please call (203) 372-0458.

July '86. Age 26. Nat'l bds. AB elig. MD, Hahnemann University, Philadelphia, PA; Int. and Res., Somerset Medical Center and Somerset Family Practice, Somerset Medical Center, Somerset, NJ. Prefers group or associate type practice. Write, James E. Barr, M.D., 207 Brooks Blvd., Manville, NJ 08835.

July '86. Age 28. Nat'l bds. AB elig. MD, Temple University School of Medicine, Philadelphia, PA; Int. and Res., Akron City Hospital, Akron, OH. Prefers group or associate type practice in a small to medium-sized community. Write, Carl G. Koplin, M.D., 2462 Eastlawn Ave., Akron, OH 44305.

Jan. '86. Age 33. Presently in practice. Nat'l bds. AB cert. MD, S.U.N.Y., Downstate; Int. and Res., Geisinger Medical Center. Prefers solo, group or associate type of practice in a medium-sized community. Write Salvatore Perconte, M.D., 11 Sol Dr., Carmel, NY 10512.

GENERAL PRACTICE

Availability open. Age 45. Presently in practice. MD, Taiwan National Medical Center; Int., St. John General Hospital, Canada; Res., Victoria General Hospital, Canada; Fellowship, Col. Belcher Hospital, Canada. Prefers group, institutional or solo type practice. Looking for a position as a general physician with or without surgery. Willing to work in a state hospital or correctional medical institution. Write, Tom C. Ho, M.D., 1130-5 Street, N.E., Minot, ND 58701.

INTERNAL MEDICINE

July '86. Age 28. Nat'l bds. AB elig. MD, Emory University; Int. and Res., Emory University affiliated. Prefers group or associate type practice in a medium to large-sized community and is interested in general internal medicine and intensive care. Write, Ronald S. Szabo, M.D., 812 Regency Woods Dr., Atlanta, GA 30319.

GASTROENTEROLOGY July '86. Age 32. FLEX. AB elig. MD, St. George's University School of Medicine; Int., Franklin Square Hospital, Baltimore, MD; Res., Union Memorial Hospital, Baltimore, MD; Fellowship, The Western Pennsylvania Hospital, Pittsburg, PA. Prefers associate, group or solo type practice in a medium to large-sized community. Write CSMS, ISG/IM.

July '86. Age 28. FLEX. AB elig. MD, University of Mississippi, Jackson, MS; Int. and Res., The Miriam Hospital, Providence, RI. Prefers solo, group or associate type practice in a small to medium-sized community. Write, Morris R. Hamilton, M.D., 12 Summit Ave., Providence, RI 02906.

OPTHALMOLOGY

Nov. '85. Age 31. Presently in practice. Nat'l bds. AB cert. (PED); AB elig. (OPTH). MD, Chicago Medical School, Chicago, IL; Int. and Res., North Shore University Hospital; Fellowship, SUNY-Downstate Medical Center. Mostly interested in a group practice in general ophthalmology. Write, Andrew E. Gewirtz, M.D., 64 Pond Rd., Apt. G-3, Woodbury, NY 11797.

ORTHOPEDIC SURGERY

Anytime availability. Age 50. Licensed in Connecticut. Presently in practice. Quebec Orthopaedic Boards. MD, University of Ottawa, Ontario, Canada; Int., Fairview Park Hospital, Cleveland, OH; Res., Akron General Hospital, Akron, OH. Prefers solo, group, associate or industrial type practice. Write CSMS, BP/ORTHO.

PEDIATRICS

Immediately available. Age 34. Licensed in Connecticut. Nat'l bds. AB elig. MD, University of Arizona College of Medicine; Int. and Res., Phoenix Children's Hospital. Prefers a group type practice. Write, Nicholas J. Argyros, M.D., 544 Prospect Ave., Hartford, CT 06105.

RADIOLOGY

July '86. Age 29. Presently in practice. Nat'l bds. AB elig. MD, SUNY Upstate Medical Center, Syracuse, NY; Int. and Res., University Hospital, SUNY at Stony Brook, NY. Prefers a group type practice in a medium-sized community. Has special training in Magnetic Resonance Imaging. Write, Brian J. Grogan, M.D., B-8 Lake Court, Middle Island, NY 11953.

Immediately available. Age 70. Licensed in Connecticut. Nat'l bds. AB cert. MD, Medical College of Virginia; Int. and Res., Beth Israel Hospital, Boston, MA; Fellowship, Pratt Diagnostic Hospital (N.E. Medical Center). Retired from Yale University. Seeking part-time activity or locum tenens. Write CSMS, SB/RAD.

Immediately available. Age 33. Presently in practice (part-time). Licensed in Connecticut. Nat'l bds. AB cert. MD, George Washington University School of Medicine, Washington, DC; Int. and Res., SUNY, Upstate Medical Center, Syracuse, NY; Fellowship, CT/Ultrasound and SUNY. Seeking locum Tenens, part-time or permanent position. Will consider any type of practice or size of community. Write, Douglas B. Bober, M.D., 47 Strawberry Lane, Manchester, CT 06040.

SURGERY

CARDIOTHORACIC. Immediately available. Age 35. Nat'l bds. AB cert. MD, Albert Einstein College of Medicine, New York; Int. and Res., Alton Ochsner Medical Foundation, New Orleans, LA; Fellowship, University of Medicine & Dentistry of NJ. Prefers associate type practice. Write Dan Morgenstern, M.D., 8 Allwood Terrace, Livingston, NJ 07039.

July '86. Age 31. Nat'l bds. AB elig. MD, University of Connecticut School of Medicine; Int., Albany Medical Center Hospital, Albany, NY; Res., Albany Medical Center Hospital and University of Medicine & Dentistry of New Jersey. Prefers group or associate type practice in a large-sized community. Write, Richard Jay Karol, M.D., 15 Lyric Court, Towson, MD 21204.

Jan. '86. Age 35. Presently in practice. Nat'l bds. AB cert. MD, Cornell University Medical College; Int., University of Texas; Res., St. Lukes-Roosevelt Hospital, NYC. Prefers group, associate or institutional type practice. Write CSMS, c/o BAB/SUR.

July '86. Age 30. Nat'l bds. AB elig. MD, University of Chicago; Int. and Res., Massachusetts General Hospital; Fellowship, University of Chicago. Prefers group practice. Write, Steven H. Untracht, M.D., 224 Kennedy Drive, #310, Malden, MA 02148.

Oct. '86. Age 32. Presently in practice. Nat'l bds. AB cert. MD, Albany Medical College; Int. and Res., St. Elizabeth's Hospital, Boston, MA. Prefers group practice. Write Richard K. Howard, M.D., 10202 Parkwood Drive, Kensington, MD 20895.

SURGICAL ONCOLOGY. Jan. '86. Age 38. Nat'l bds. AB cert. MD, Int., American University of Beirut, Lebanon; Res., St. Luke's-Roosevelt Hospital, NYC; Fellowship, Memorial Sloan Kettering Cancer Center, NYC. Prefers group, associate or institutional type practice. Write, CSMS, c/o ASM/SUR.

Cholesterol: What it Means in 1986

FRANK DAVIDOFF, M.D.

Cholesterol remains a major and growing preoccupation of American patients and their physicians.[1] Until very recently, however, the exact implications of serum cholesterol levels were at best hazy and at worst highly controversial.[2] In the two years since I last commented in these pages on lipids and heart disease[3] important new information has become available on the effects of interventions to lower serum cholesterol, primarily from the Lipid Research Clinics (LRC) controlled trial.[4] These data significantly increase our confidence in the meaning of any given cholesterol level, and, therefore, should at last provide a solid basis for all of us, patients and physicians alike, on which to decide a reasonable course of action. Several summaries of the current state of information in this area have appeared recently.[5-7]

Before going into the results of the LRC trial in detail it is worth reviewing the epidemiological information which links serum cholesterol to heart disease. The evidence relevant to this link has also continued to develop in the past several years, and provides an important background to any discussion of interventions which lower serum cholesterol.

The Many Predictors of Cardiovascular Disease

The epidemiological data, particularly from the Framingham study,[8] overwhelmingly link a wide variety of factors – including age, sex, hypertension, smoking, and diabetes – to the risk of developing cardiovascular disease, particularly coronary disease. To many clinical scientists, such evidence suggests that atherosclerotic disease is directly caused by a combination of these factors acting in concert – a "multifactorial model" of disease etiology. To others, multifactorial models are unacceptable. In the latter view, a single, primary cause will ultimately be found for every disease including coronary atherosclerosis, in just the way the pneumococcus emerged as *the* cause of pneumococcal pneumonia, and our present need to invoke multiple "risk factors" will be seen as a reflection of the profundity of our present ignorance about disease mechanisms.

While the scholarly critics of the multifactorial etiology of atherosclerosis may ultimately turn out to be correct, there is no denying the awesome power of these multiple risk factors as predictors of the occurrence of coronary disease. Thus, in Table 1, we can see that the presence of only four risk factors is associated with a 140-fold increase in risk of a coronary event. This predictive power is sufficiently great that, in my view, the possibility of multifactorial causation for coronary atherosclerosis must be taken seriously.

Table 1
RISK OF NON-FATAL MYOCARDIAL INFARCTION OR CORONARY DEATH
SIX-YEAR INCIDENCE IN MEN – FRAMINGHAM STUDY

Age	*Nonsmoker; cholesterol 185 mg/dl; diastolic BP 80*	*60 cigarettes/day; cholesterol 335 mg/dl; diastolic BP 110*
35	0.4	13.9
40	0.7	19.7
45	1.0	27.3
50	1.6	36.4
55	2.4	46.6
60	3.6	57.1

Among the identified risk factors for cardiovascular disease, the total level of serum cholesterol has emerged as one of the most important and enduring. As noted previously,[3] however, just because such a relationship exists does not mean that the relationship is simple. Remember that we are not discussing here the unusual patient with very high cholesterol levels (over 350 Mg/dl) and a family history consistent with autosomal dominant hypercholesterolemia (so-called Type IIa hyperlipidemia). While even in the autosomal dominant disease the prediction of actual coronary risk is not always simple,[9] there is really no argument about increased risk in these families.

Looking at the rest of the "normal" population, the risk of a coronary even does, in a general way, increase with total serum cholesterol, but that risk does not, in fact, *always* increase in direct or constant proportion to the increase in total cholesterol, even when other known nonlipid risk factors are held constant. Indeed, over the years the ambiguity of the relationship between total cholesterol and coronary risk has been a major source of confusion and frustration for physician and patient alike.

The difficulty in interpreting the clinical significance any given total cholesterol level has several major sources.

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First, the *absolute* increase in risk with increasing cholesterol depends on the presence or absence of other risk factors (Figure 1). Thus, for example, the risk of experiencing a coronary event goes up only by about 2.9 (the eight-year probability of a coronary event per 1,000 subjects at risk) in a normotensive, nonsmoking, nondiabetic man without left ventricular hypertrophy (LVH) as the total cholesterol level increases from 185 to 335 mg/dl, while the increase in risk is 43.2 in a male hypertensive smoker with LVH and glucose intolerance as the cholesterol increases over the same range.[8] Clearly, your "cholesterol" means very different things, depending on who you are.

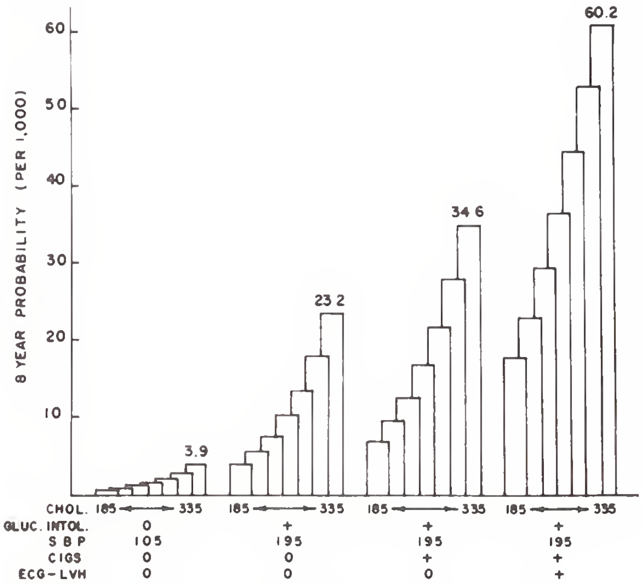

Figure 1

Data from the Framingham study[8] demonstrating 8-year risk of a cardiovascular event according to total serum cholesterol at specified levels of other risk factors for men aged 35 years.

Abbreviations: CHOL = total cholesterol; GLUC INTOL = glucose intolerance; SBP = systolic blood pressure; CIGS = cigarette smoking; LVH = left ventricular hypertrophy.

Second, while there is no argument that the total cholesterol is a predictor of coronary disease, *by itself* the quantitative predictive power of the total cholesterol turns out to be relatively weak. Indeed, in the past decade it has become clear that among the lipids in plasma, by far the *single* best predictor of coronary disease is the high-density lipoprotein cholesterol (HDL-C), a fraction which makes up anywhere from about 10-40% of the total circulating cholesterol. Most of the remaining cholesterol circulates bound to low-density lipoprotein (LDL-C); *by itself* the LDL-C fraction turns out to predict coronary risk only about half as well as the level of HDL-C; the total cholesterol level (T-C) alone ranks a distant third among these three measurements as a predictor of coronary risk.

Third, not all cholesterol in plasma is "bad." By this is meant, of course, that while the risk of coronary disease generally goes *up* with increasing T-C level and always goes up with increasing LDL-C level, risk goes *down* with increasing levels of HDL-C. One major reason for the poor performance of T-C in predicting coronary risk is therefore obvious, since a rise in total cholesterol due solely to an increase in the HDL-C fraction would actually *diminish* your coronary risk.

It should not be surprising, therefore, to learn that when both T-C and HDL-C levels are used together to predict coronary disease, their combined predictive power, as, for example, the ratio of T-C/HDL-C, is greater than that of either value alone.[10] What's more, if the information contained in the level of either the T-C, LDL-C, or LDL-C is used in addition to the information in the T-C/HDL-C ratio, the power to predict coronary risk does not increase beyond the power provided by the ratio itself. Translated into clinical terms, this means that, at least as far as circulating lipids are concerned, a patient with a T-C/HDL-C ratio of five is at the same degree of coronary risk whether that ratio of five comes from measured cholesterol levels of 375/75 or 250/50 or 180/36. (The LDL-C/HDL-C ratio also provides most of the predictive power of circulating cholesterol, although for men with any given ratio of LDL-C/HDL-C coronary risk is greater when the denominator of that ratio is a low HDL-C level than when it is high HDL-C.)[10] The development of these improved indices of coronary risk is reflected in the practice of many clinical laboratories which now routinely perform both T-C and HDL-C measurements, calculate the ratio, and indicate relative cardiovascular risk in their reports to physicians.

The Sensitivity and Specificity of Total Cholesterol Measurements in Estimating Coronary Risk

The ability to predict coronary risk directly from measured cholesterol levels is an unusual circumstance in clinical medicine; indeed, it is virtually unique, made possible only by the unusually complete, prospective epidemiological design of the Framingham study and others like it. In effect, these studies directly measured *the likelihood that a patient whose other risk factor status is known will develop a coronary event, given a certain cholesterol level.* Calculation of this likelihood is a formal and explicit procedure which parallels the implicit and intuitive reasoning physicians use for making diagnoses, a kind of diagnostic index, therefore. This particular index, which is of fundamental importance, is now known technically as a "predictive value," in this instance, a positive predictive value because an elevated cholesterol level is taken to represent a "positive" test result.[11] In contrast, the usual lab test does not predict disease directly. Instead, two other measurements of the test's diagnostic power, "sensitivity" and "specificity," are determined, and used, along with the pre-test disease likelihood, to calculate the predictive value – which is really just a revised, post-test disease likelihood, for any given patient.

The sensitivity of a test is *the likelihood the test will be positive, given the presence of disease* – the exact opposite of predictive value – while its specificity is *the* *likelihood the test will be negative in the absence of disease.* From the Framingham data we can get an idea of the sensitivity and specificity of the total serum cholesterol as a test to predict coronary risk, which provides us with a more familiar way of looking at its ability to predict disease and the sources of weakness in making that prediction.

Since coronary risk increases as T-C rises above the level of 175 mg/dl, we would be justified in saying that any T-C above this cutoff level is "abnormal." When we do so, we find from the Framingham data, Figure 2,[8] that the likelihood of the initial T-C level being abnormal, i.e. over 175 mg/dl, in those subjects who developed coronary events (that is, the likelihood of a *true positive result*) is extremely high. More specifically, about 95% of those subjects who developed clinical coronary disease over a 16-year period had "positive tests" (dotted curve in Figure 2), or, in more technical terms, the test's *sensitivity* is in the range of 95%, which is excellent. Unfortunately, however, using the same cutoff level of 175, the likelihood of finding an abnormal test (above 175 mg/dl) in those Framingham subjects who did *not* experience a coronary event, is also very large, about 75% (solid curve in Figure 2); that is to say, the number of *false positive* results, is also extremely high; as a result the *specificity* of the test is extremely poor.

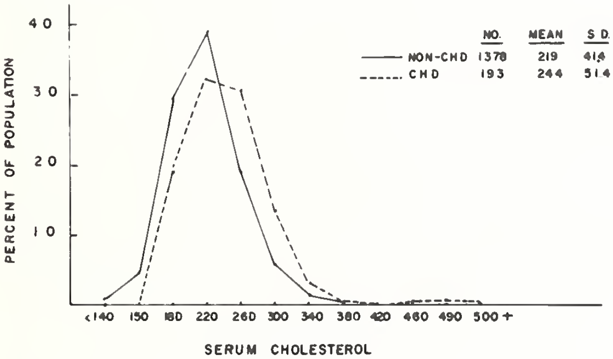

Figure 2

Distribution of total serum cholesterol levels (mg/dl) in subjects free of coronary heart disease vs. those developing coronary heart disease over 16 years of follow-up. Data from the Framingham study [8] for men aged 30-49 years at entry. CHD—coronary heart disease.

Indeed, the specificity of the total cholesterol level as a measure of coronary risk does not even begin to improve unless and until we raise the cutoff level between normal vs. abnormal to about 250 mg/dl, and it is not until the cutoff is raised to 300 that test specificity becomes at all respectable. Looking at the diagnostic performance of the total cholesterol from the more conventional point of view of its sensitivity and specificity, it is evident, therefore, that at cutoff levels below 250 mg/dl the weak predictive value of the total cholesterol primarily derives not from poor sensitivity—indeed, sensitivity is very good—but rather from poor test specificity—the dilution of true positives with a large number of false positive results. As the cutoff is raised progressively above 250 mg/dl, the specificity of T-C improves, but the test becomes less sensitive to the presence of coronary disease. Finally, the predictive value of a positive test becomes quite good when the cutoff for total cholesterol level is in the range of 300, but only at the expense of creating a negative test which is weak in its ability to predict correctly the absence of disease. This description of the imperfect sensitivity and specificity of the total cholesterol as a test for coronary disease can also be viewed as a somewhat more technical way of describing the tremendous overlap of the two distribution curves for total cholesterol levels which is obvious simply on inspecting Figure 2.

The Lipid Hypothesis: Closing the Loop

The "lipid hypothesis" states that serum cholesterol plays an etiological role in the causation of atherosclerosis, particularly of the coronaries. If the lipid hypothesis were true, not only should the naturally occurring levels of serum cholesterol be strong, if not perfect, predictors of coronary disease (Figure 3A) but also it should be possible to "close the loop" of evidence by demonstrating that interventions which lower T-C or LDL-C, or those which raise HDL-C, reduce risk (Figure 3B). In the absence of appropriate responses to such interventions, the evidence supporting the lipid hypothesis remains largely an association, a correlation between cholesterol levels and coronary risk, and, as everyone knows, the history of medicine is littered with correlations, weak and strong, which suggested a cause-and-effect relationship but which turned out to be coincidences rather than causalities.

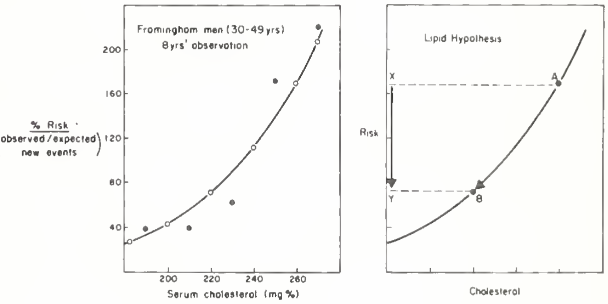

Figure 3

Graphic representation of the Lipid Hypothesis.[13] A (left): Coronary risk in relation to observed total cholesterol level. B (right): Demonstration of the Lipid Hypothesis that intervention to lower total cholesterol reduces risk from X to Y.

In past years, the uncertainty and inconsistency of serum cholesterol levels as predictors of coronary disease have been compounded by the inability to demonstrate convincingly that interventions which lower the T-C or LDL-C reduce coronary risk, despite several major studies designed to do just that. We still lack such evidence for interventions which raise the level of HDL-C, but in recent years we have at last received evidence that lowering T-C and LDL-C does, indeed, reduce coronary risk. Indeed, the information is of sufficient quality that now it is possible to say not only that lowering cholesterol reduces coronary risk, but also to say how much risk reduction accompanies a given decrease in cholesterol level, and roughly how long it takes for this protective effect to become manifest. In sum, the case for the lipid hypothesis has been measurably strengthened.

Why was it so difficult to obtain such intervention data in the past, and what did the newer studies do to overcome those difficulties? An examination of the key features of the LRC coronary primary prevention trial gives us some clear answers to these questions.[4]

First, despite the facts that 1) coronary disease is common relative to most other diseases and 2) cardiovascular disease remains the leading cause of death in this country, the absolute rate of development of coronary disease is slow, and the absolute frequency of coronary events is small—only between 1 and 60 per 1,000 men who entered the Framingham study at age 35 developed clinical cardiovascular disease in an eight-year interval. Finding numbers of coronary events, definite and probable, large enough to reach levels that are both statistically significant and clinically meaningful requires, therefore, either that the number of subjects in the study group must be large, or they must be studied over a long period of time, or both, and the dropout rate must be small.

In order to meet this statistical objective, the LRC trial enrolled no less than 3,806 subjects, but in order to find this number who met the study criteria the investigators had first to screen nearly a half a million age-eligible men over a three-year period, a task of staggering proportions. The study was then conducted over a 7-10 year follow-up period in 12 participating study centers around the country. Follow-up was 100% for all living subjects in the study. As we will see, however, even with such a large number of subjects, a long study period, and perfect follow-up, the numbers of "hard" coronary events, i.e. coronary deaths, was only in the 30's in each group, a relatively small number.

Second, the designers of the trial wanted to avoid a major potential design flaw of some of the previous intervention trials, namely, those which had used subjects already identified as being at coronary risk by having angina or a previous myocardial infarction at the time of entry into the study. While using such subjects increased the likelihood that the number of coronary-related events, such as coronary death or non-fatal myocardial infarction, which occur during the course of the trial would be large enough to generate meaningful statistical conclusions, at the same time this study design reduces the likelihood of detecting a true reduction in risk. This apparent contradiction flows from the fact that studies of this type represent "secondary prevention" trials, that is the intervention takes place after the disease has already become clinically manifest, and with the intent of preventing its progression rather than its onset. Secondary prevention studies may be fairly criticised on the ground that by the time the subjects are exposed to the intervention the "horse is out of the barn." That is, if the study finds no evidence for risk reduction by lowering T-C or LDL-C, the explanation may lie in the far advanced state of atherosclerosis in the study subjects, since the disease may have already progressed to the point where it has become essentially irreversible, rather than because the lipid hypothesis is untrue.

At the same time, the designers of the LRC trial tried to avoid going to the opposite extreme; that is, if they had chosen study subjects whose risk of coronary disease was extremely low they might have reduced the chances of observing a sufficient number of cardiovascular events to a point that they would be unable to draw statistically meaningful conclusions, despite large numbers of study subjects and long, complete follow-up. Thus, for example, enrolling only non-smoking women ages 15 through 20 with cholesterol levels below 200 in the LRC study would certainly have established the study as a primary prevention trial (that is, an intervention prior to the onset of clinical disease and designed to prevent its occurrence), and as such would certainly have avoided studying subjects with irreversible disease. But in this case it is also virtually certain that the number of coronary events in 3,806 such subjects, even with perfect follow-up over 20 years, would have been so small as to eliminate any chance of deciding whether the intervention was effective.

The designers of the trial compromised, therefore. They chose "middle-risk" subjects: men aged 35-59 years old, with T-C levels over 265 mg/dl (the 95th percentile for men aged 40-49 years, see Figure 2)—placing them at significant risk of developing coronary events—but they excluded as a subject anyone with clinical evidence of coronary heart disease, according to history, ECG or other evidence—thus meeting the criteria for a primary prevention trial and avoiding the likelihood that the atherosclerotic process was far advanced or irreversible.

The essential core of the study was the treatment of half the subjects with a cholesterol-lowering drug: cholestyramine resin, administered in doses of up to 24 grams per day. The study was also set up to meet numerous stringent design criteria, including, among others:

- subjects were enrolled in treatment or control groups in a randomized fashion;
- the study was carried out prospectively and was blinded by giving the control subjects placebo medication;
- compliance with medication-taking was measured by counting the number of unused doses;
- the effects of other extraneous variables were controlled to the maximum possible extent, either by applying them equally to both treatment and control groups (as, for example, a cholesterol lowering diet), or by measuring the amount of the variable (for example, smoking) and tabulating the results separately for those with and without the variable, a process known as *stratification;*
- the cardiovascular outcome events were carefully defined and measured; and, finally,

- the possibility of biases introduced by chance because of major differences in study conditions from center to center were excluded by looking for extreme results at any one study center.

As might be expected, such an extensive study generated a great deal of data. However, the principal results are summarized in the following four tables. The most important findings are the figures for the "hard" coronary endpoints contained in the first two lines of Table 2. First, the number of deaths attributable directly to coronary heart disease was eight fewer in the resin-treated group than in the controls. This represents a small number of deaths out of the entire group of 3,806 subjects, but the difference between 30 vs. 38 coronary deaths, a reduction of 24%, is highly significant statistically. Perhaps as important were the 28 fewer myocardial infarctions in the treated group (130 vs. 158), a reduction of 19% which is, again, statistically significant. Together, the 36 fewer deaths and MI's in the resin group reflect 2% of the subjects at risk in that group who were apparently protected by treatment; or, looked at slightly differently, a total of 72 fewer subjects out of the original 3,806 might have experienced one of these "hard" endpoints if the entire study group had been treated with resin, compared with the number of hard endpoints if all subjects had received placebo. Seventy-two out of 3,806 begins to look quite substantial.

Table 2
END POINTS—CORONARY AND NON-CORONARY
LIPID RESEARCH CLINICS PRIMARY PREVENTION TRIAL

Event	*Placebo*	*Resin*	*%Risk Reduction*
	Number of	*subjects*	
CHD Death	38	30	24*
Nonfatal MI	158	130	19*
Death, all causes	71	68	7
+Exercise test	345	260	25*
Angina	287	235	20*
Bypass surgery	112	93	21*
CHF	11	8	28
Intraoperative MI	7	5	29
TIA	22	18	18
Stroke	14	17	−21
Leg claudication	84	72	15*

*=Statistically significant result

In lines 4-6 of Table 2 are shown the data for three "soft" cardiovascular endpoints ("soft" because they provide less perfect evidence that coronary disease was present, and because of the larger role of subjective judgment in their interpretation): the development of a positive exercise test during the course of the study; the new onset of angina; and the performance of coronary bypass surgery. In all three instances, there was a reduction in risk in the range of 20-25%; all were statistically significant. The apparent protection against these "soft" endpoints by resin therapy extended extended to 156 subjects, nearly 10% of the at-risk subjects in the treatment group.

This table also indicates that there were no significant differences between the two groups in the occurrence of several other cardiovascular events, i.e. congestive failure, intraoperative myocardial infarction, TIA, or stroke, but that 12 fewer resin-treated subjects developed leg claudication, a result which was statistically significant. Because of concerns raised from other studies about a possible increase in cancer risk associated with marked lowering of cholesterol in general, and in the rate of gallstone formation associated with other cholesterol-lowering drugs, it is important also to note that cancers and gallstones developed during the course of the study at rates which were not different in the treatment vs. control groups.

During the first year of study, T-C level fell by an average of 42 mg/dl from the baseline value in the resin-treated group, compared with a mean fall of only 4 mg/dl in the control group. The amount of the decrease was not sustained over time, however, shrinking to 23 vs. 2 mg/dl below baseline in the treated and control groups, respectively, after seven years. LDL-C levels also fell in the two groups by an amount slightly greater than the fall in total cholesterol, but the level of HDL-C rose slightly, by 2 mg/dl, during the course of the study. The postulates of the lipid hypothesis were, therefore, fulfilled: the differential decrease in coronary morbidity and mortality between the two groups was a concomitant of a differential decrease in total (and in LDL) cholesterol, which occurred in the absence of a significant change in HDL-C level.

Since the only known difference between the treatment vs. control group was the use of pharmacologically active resin, it seems reasonable to attribute the greater fall in cholesterol in the treated group to the use of the resin. Such all-or-nothing conclusions about a treatment are always strengthened if a "dose effect" can also be demonstrated—in this instance, a dose effect would be manifest if the drop in cholesterol level were greater at larger doses of resin. By measuring compliance, the LRC investigators knew just how much resin each subject actually took, on average, and therefore could assess cholesterol decreases in groups of subjects who ingested resin in different doses. The data in Table 3 demonstrate just such a dose effect over the entire range of resin doses: those who took the "full" 24 gm-dose of resin daily experienced an average decrease of 28% in LDL-C, almost a 50% greater decrease than for the resin group as a whole.

Table 3
DOSE-RESPONSE OF CHOLESTEROL TO MEDICATION

Packet count (Mean daily)	*% Change Total C*	*% Change LDL C*	*% Change HDL/Total C*
0-1	−3.9	−6.6	+10.8
1-2	−5.4	−8.7	+10.1
2-3	−8.2	−13.1	+17.2
3-4	−11.1	−16.5	+22.3
4-5	−14.0	−20.9	+23.5
>5	−19.0	−28.3	+32.3

While the number of subjects was not large enough to demonstrate in detail that the resin dose-effect also extended to cardiovascular "endpoint" as well as to cholesterol decreases, it is not unreasonable to suspect that those subjects who took the largest amounts of resin not only lowered their cholesterol levels the most but that on average probably also experienced the lowest cardiovascular risk. The data in Table 4 do not fully demonstrate a dose effect of resin dose on cardiovascular events themselves, but do provide limited support for such a dose effect on coronary risk; thus, mean LDL-C levels in all subjects, resin-takers or not, who experienced cardiovascular events in any given year of the study were significantly higher than LDL-C levels in all those who were free of such events in that same year, with the exception of the first and the sixth years. The failure to find a difference in LDL-C levels in afflicted vs. healthy subjects during the first year of the study suggests that protection against cardiovascular risk due to cholesterol lowering, by resin or otherwise, takes at least one year to become manifest. The apparent time lag in protection is congruent with what is known about the slow pace of development of coronary atherosclerosis, which is estimated to spread to cover the coronary endothelial surface in men at a rate of only 1-3% per year after age 20.[6]

Table 4

% CHANGE IN LDL-C WITH AND WITHOUT CHD END POINT–BY YEAR

	Year of followup							
	1	2	3	4	5	6	7	8+
No CHD Event	−24.9	−21.0	−19.9	−18.9	−18.4	−17.9	−16.9	−15.8
CHD Event in Year	−26.1	−16.9	−12.9	−7.1	−12.2	−18.5	−10.1	−5.8

The data from the LRC trial are of sufficient quality and detail to calculate the amount of reduction in coronary heart disease incidence for any given reduction of cholesterol below the baseline value. Table 5 presents the results of those calculations, done independently for subjects in the placebo group and the resin group, and by a slightly different method for both groups combined. Decreases in LDL-C in the placebo group must obviously have been due to factors other than resin treatment, but resin-induced or spontaneous, a given percentage decrease in cholesterol is associated with coronary risk reduction which is strikingly similar in the two groups. The general conclusion is that the percent reduction in risk is equal to approximately twice the percent reduction in LDL-C; thus, for example, a 10% reduction in cholesterol is associated with about a 20% decrease in risk.[4,7] These figures are consistent with the changes in risk inferred from observational, epidemiological data, and, of course, represent average changes. Particularly in the presence of other risk factors, cardiovascular risk reduction may well be greater than the amounts indicated in Table 5, for any given decrease in cholesterol level.

Finally, the LRC data suggest that concerns about dietary auto-oxidation products of cholesterol as the "real" etiological agents in the pathogenesis of atherosclerosis[12] may be unfounded. After all, if auto-oxidized cholesterol in the diet really caused the mischief, why should cholesterol lowering in plasma reduce coronary risk, unless cholestyramine also binds these cholesterol oxidation products in the gut, thus preventing their absorption?

Table 5

REDUCTION IN CHD INCIDENCE PER 22.3 MG/DL DECREMENT IN LDL-C LEVEL

Treatment	*% Decrement*
Placebo	16.0
Resin	17.2
Both	18.8

Should Everyone with Total Cholesterol Levels over 175 mg/dl Be Treated?

It was not so long ago that the basic question in the management of hypercholesterolemia was "Not how, but whether?",[13] and that representatives of the nutrition committee of the American Heart Association could write: "Many, but clearly not all, investigators believe that reduction of plasma cholesterol and LDL-C levels would retard the progression of atherosclerosis, but opinions on the strength of the probability vary widely . . . A reasoned resolution of the controversy is not currently possible."[14]

With the "closing of the loop" of evidence for the lipid hypothesis, the case for treating increased cholesterol levels in a effort to reduce cardiovascular risk is obviously materially strengthened. However, before such policies and practices are adopted in "knee-jerk" fashion, it is essential to look at all sides of the question, in particular the amount of protection achieved relative to the discomfort, risk and cost incurred.

First, strictly speaking, the LRC trial did not demonstrate that all treatments which lower T-C or LDL-C are effective, since the only treatment actually studied was cholestyramine resin. However, protection also appeared to extend to those subjects in the placebo group whose cholesterol decreased "spontaneously" (see Table 5). It seems highly unlikely, therefore, that there is anything biologically or pharmacologically unique to cholestyramine resin in its ability to reduce cardiovascular risk, and these results can presumably be extrapolated to any and all treatments which lower LDL cholesterol. Again, in strictest terms, the LRC trial did not demonstrate that lowering cholesterol in patients whose T-C levels are initially below 265 mg/dl is clinically effective in reducing the risk of cardiovascular events. However, it is also difficult to believe that a T-C level of 265 mg/dl represents some kind of "threshold" for protection, which would imply that patients whose initial T-C is above 265 mg/dl are uniquely susceptible to the beneficial effects of cholesterol reduction.

Even assuming that the LRC results can be extrapolated to all treatments that lower LDL-C, and to any patient with a T-C over 175 mg/dl, however, the results of the LRC trial do not really change the previous suggestion[3] that treating a high cholesterol, including one as high as

335 mg/dl, may not be appropriate in some subjects, particularly those with no other known risk factors, particularly if his or her T-C/HDL-C ratio is low, because the absolute decrease in cardiovascular risk may simply be too small to be considered worth while. In contrast, the LRC trial certainly encourages treatment of patients whose cholesterol levels are at the high end of the normal distribution curve when many other risk factors are present, and may lower the threshhold for treating those with cholesterol values in the middle of the distribution curve, i.e. in the 250 range, in the presence of some other risk factors.

Cholestyramine resin therapy itself presents special problems. Taking full doses of this medication is like swallowing fine sand six times a day; gastrointestinal symptoms are not uncommon in patients taking the resin (although in the LRC trial these were about as common in the patients taking placebo medication); and the active resin can interfere with the absorption of other drugs and some vitamins.

Not the least consideration in all of this is the cost of resin therapy. The annual cost for the resin alone, not including the cost of physician visits, repeated cholesterol determinations, etc. may be as high as $1,861,500 (in 1984 dollars) per 1,000 people treated.[15] This results in a cost ranging from $775,600 to $9,307,500, depending on how the calculation is done, to prevent one myocardial infarction or coronary death. According to this analysis, resin therapy to lower cholesterol does not rank high in the hierarchy of cost-effectiveness, since this approach to therapy costs roughly 2-15 times more than it would cost per death (from any cause) prevented by providing free care to everyone.

Is it worth treating patients to lower their serum cholesterol levels? The answer in 1985, as it was in 1983, is still "It depends." The difference is that now we can think about this question more clearly and quantitatively, hence decide on an optimal course of action for each individual patient more rationally than we could even two years ago.

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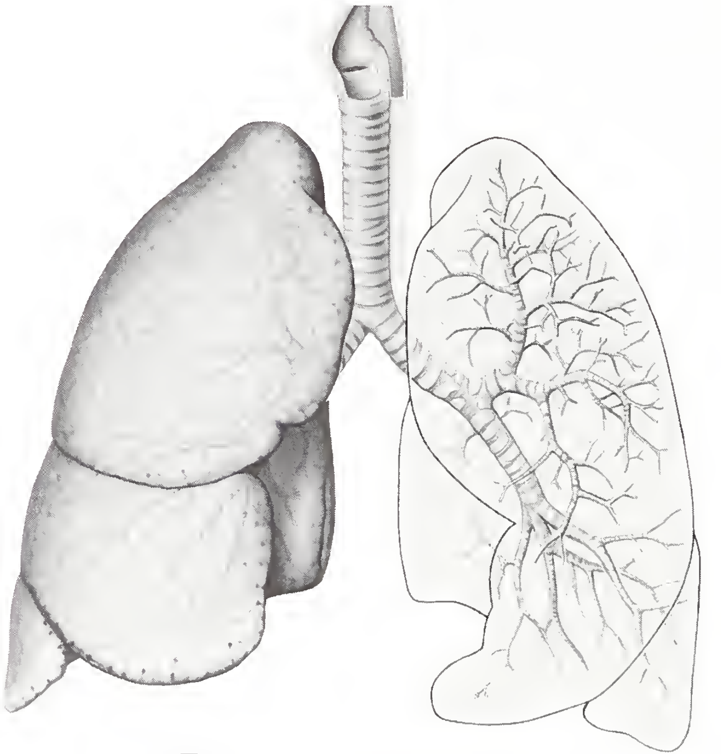
Consider the causative organisms...



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Indications and Usage Ceclor® (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms

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Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics

Warnings IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins), therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics Such colitis may range in severity from mild to life-threatening

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C difficile* Other causes of colitis should be ruled out

Precautions *General Precautions* — If an allergic reaction to Ceclor® (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e g , pressor amines, antihistamines, or corticosteroids

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug

Ceclor should be administered with caution in the presence of markedly impaired renal function Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly)

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis

Usage in Pregnancy — Pregnancy Category B — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor® (cefaclor, Lilly) There are, however, no adequate and well-controlled studies in pregnant women Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses Average levels were 0 18, 0 20, 0 21, and 0 18 mcg/ml at two, three, four, and five hours respectively Trace amounts were detected at one hour The effect on nursing infants is not known Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below

Gastrointestinal symptoms occur in about 2 5 percent of patients and include diarrhea (1 in 70)

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely

Hypersensitivity reactions have been reported in about 1 5 percent of patients and include morbilliform eruptions (1 in 100) Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor Such reactions have been reported more frequently in children than in adults Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy No serious sequelae have been reported Antihistamines and corticosteroids appear to enhance resolution of the syndrome

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients)

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40)

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[0617B2R]

Note Ceclor® (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Osteogenic Sarcoma Simulating Bronchogenic Carcinoma

ERIC TEN BROCK, M.D., JOHN VOTTO, D.O. AND DAVID FREDERICK, M.D.

ABSTRACT—A case of osteogenic sarcoma is presented in which an endobronchial lung metastasis is diagnosed eight years after amputation of the primary lesion. This is the longest disease free interval reported as well as the first case which presented as endobronchial obstruction. Clinical and radiographic patterns of pulmonary metastases in osteogenic sarcoma are reviewed.

Introduction

Both the natural history and metastatic pattern of osteogenic sarcoma may be changing.[1, 2] We present a case of a 26-year-old male whose clinical presentation as well as radiographic and bronchoscopic findings are more consistent with primary bronchogenic carcinoma.

Case Report

A 26-year-old male was admitted to the Newington V.A. Medical Center because of a left upper lobe mass lesion on chest radiograph which was obtained because of a complaint of six months of nonproductive cough (Figure 1). His right leg was amputated above the knee for osteogenic sarcoma at age 18, and he subsequently received adjuvant chemotherapy consisting of metrotrexate, cytoxan, adriamycin and vincristine for two years. He was followed at six month intervals for four years and was disease-free, then was lost to follow-up until presenting at this admission.

On exam he was a healthy appearing man in no distress. The lungs were clear, there was no clubbing, lymphadenopathy or organomegaly. The remainder of the exam was unremarkable as were the laboratory values. A fiberoptic bronchoscopy was performed and revealed an endobronchial mass lesion obliterating the left upper lobe bronchus but not the lingular bronchus; also, there was a 0.5 x 0.5 cm nodular lesion in the left mainstem bronchus. Biopsies examined under light microscopy were not diagnostic; however, sections examined under electron microscopy revealed findings diagnostic of osteogenic sarcoma including osteocytes with scalloped nuclei, glycogen granules and dilated endoplasmic reticulum (see Figure 2). Within one week of diagnosis the patient developed hoarseness and laryngoscopy revealed left vocal cord paralysis, thus obviating the possibility of a curative surgical resection. He was treated with carboplatin, a cisplatin analog, with transient reduction in the tumor size, followed by a regimen consisting of bleomycin, cytoxan, and dactinomycin. Ten months after initiation of chemotherapy, his chest radiograph demonstrated enlargement of the left upper lobe and hilar mass.

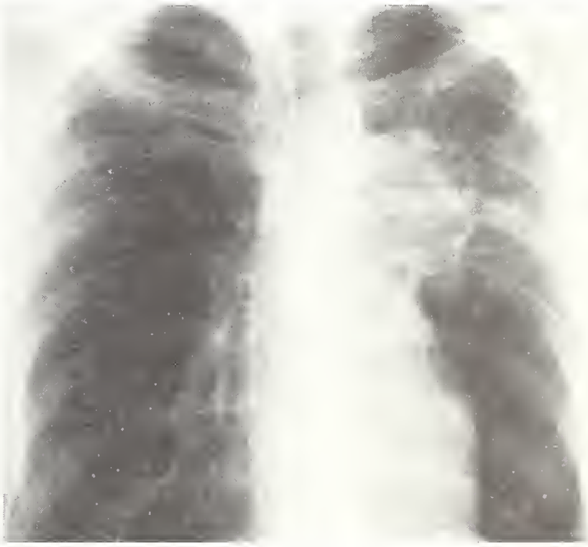

Figure 1

Admission chest radiograph showing a solitary central left upper lobe mass.

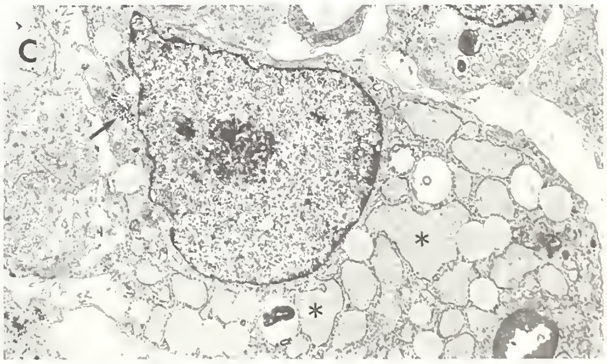

Figure 2

Electron micrograph revealing osteocytes. Present is collagen (C), glycogen granules (arrow), and dilated endoplasmic reticulum (*).

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Discussion

We have presented a patient who developed osteogenic sarcoma at age 18 treated with amputation and adjuvant chemotherapy, and after an eight year disease-free interval presented with a solitary central, obstructing endobronchial mass. The natural history as well as the radiographic and bronchoscopic findings of this case are distinctly unusual for metastatic disease from osteogenic sarcoma. Pulmonary metastases from osteogenic sarcoma are extremely common. However, Marcove,[3] in a review of 145 operative cases, stated that the incidence of pulmonary metastasis developing more than two years after diagnosis was "very close to zero." In fact, the mean duration from amputation to clinically evident pulmonary involvement was 8.5 months, and the longest interval in the literature is 68 months. This patient's disease-free interval was 90 months.

It is tempting to speculate that adjuvant chemotherapy extended the disease-free state in this individual. However, recent evidence suggests that adjuvant chemotherapy is associated with an increased incidence of extrapulmonary metastases but does not alter the occurrence of pulmonary metastases compared to amputation alone.[1] The usual radiographic pattern of pulmonary metastases is that of multiple peripheral nodules, often bilateral, usually less than 3 cm in diameter, which not infrequently calcify. A large solitary mass with a grossly visible endobronchial obstructing lesion is typical of bronchogenic carcinoma but has never been reported in osteogenic sarcoma. In an autopsy series of 130 extrathoracic tumors with pulmonary metastases including 22 sarcomas, none of the sarcomas had visible endobronchial involvement of a major bronchi.[4] King and Castleman's[5] autopsy study of 109 patients with metastases to the lung with bronchial involvement included six sarcomas but only one osteogenic sarcoma. This one case, like others reported, had only microscopic evidence of bronchial invasion.

This case, along with recent data suggesting a change in the natural history of osteogenic sarcoma, illustrates the need for extended evaluation for recurrence of disease as once symptoms occur curative surgical resection is frequently not possible.

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Borderline Ovarian Tumors

DAVID BRUMLEY, M.D.

ABSTRACT—During a ten year period, four cases of borderline ovarian tumors were found in a series of 50 primary ovarian neoplasms. This relatively new classification arose from recognition of a benign clinical course in patients with tumors of this type. These have been classified according to histologic criteria regardless of clinical manifestations.

In this series, age at presentation ranged from 30 years to 60 years. Three of the four presented with complaints of abdominal swelling for between one to twelve months. One presented with a two month history of intense pelvic cramping. In three cases, abdominal masses were palpated. A left adnexal mass was found in the fourth. Bilateral mucinous tumors were found in one instance and bilateral serous tumors in another. Treatment of these tumors consisted of total abdominal hysterectomy, bilateral salpingo-oophorectomy and omentectomy in three, with the fourth managed by left oophorectomy and right ovarian wedge resection. All four cases were alive and well at last follow-up which has ranged from six months to four and one-half years.

Unilateral tumors may be managed with unilateral salpingo-oophorectomy and later pelvic clearance in women of childbearing age. Bilateral salpingo-oophorectomy, total abdominal hysterectomy, and omentectomy is recommended for older patients, those with bilateral tumors or with extraovarian extension.

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This paper was presented at the Second CSMS Residents' Symposium on Cancer as part of the 193rd Annual Meeting of the Connecticut State Medical Society held in New Haven, CT on May 9, 1985.

Introduction

In a series of 50 primary ovarian tumors removed at St. Joseph Hospital between 1975 and 1984, 45 (90%) were epithelial tumors. (See Table 1). Four (8%) were classified as borderline malignancy type. (See Table 2). The category of borderline ovarian tumors arose from recognition by Taylor in 1929 of a distinct group of patients with surface epithelial tumors having some malignant pathologic features and often apparent metastases, but which pursued a benign clinical course. About 30 years elapsed before this category was recognized by FIGO and WHO.

Table 1

50 CASES OF PRIMARY OVARIAN CANCER 1975-1984

Adenocarcinoma and Undifferentiated Carcinoma	18 (36%)
Serous Cystadenocarcinoma	9 (18%)
Mucinous Cystadenocarcinoma	6 (12%)
Endometrioid Carcinoma	7 (14%)
Serous Tumor Borderline Malignancy	2 (4%)
Mucinous Tumor Borderline Malignancy	2 (4%)
Granulosa Cell Tumor	2 (4%)
Teratocarcinoma	2 (4%)
Endodermal Sinus Tumor	1 (2%)
Mesonephric Tumor	1 (2%)
	50 (100%)

Case Reports

Case #1 is a 55 year-old G2P2. Presenting complaint was an enlarging abdomen for four years. Family history was remarkable for a mother with an ovarian carcinoma. On physical examination a large protruding, non-pulsatile abdominal mass was found. Pelvic ultrasound and computed tomography showed an ovarian mass. An extrinsic mass with colon displacement was seen on barium enema and an intravenous pyelogram revealed mild ureteral dilation. A total abdominal hysterectomy, bilateral salpingo-oophorectomy, and partial omentectomy were performed. The mass was found to be adherent to the omentum and transverse colon. There were no implants seen and the right ovary was normal. Histologic diagnosis was borderline mucinous cystadenoma. The patient did well postoperatively and at last follow-up seven months later was alive and well.

Case #2 is a thirty-five year old G2P2. Abdominal bloating and vaginal discharge were the chief complaints. No abdominal mass was palpable. On pelvic examination a five centimeter irregular, doughy, left adnexal mass was found. Dilatation and curettage, left oophorectomy, right ovarian wedge resection, and peritoneal washings were performed. Findings were a papillary borderline serous cystadenoma with no evidence of extensions. The patient had no evidence of disease one year postoperatively.

The third case is a thirty-nine old GoPo. An abdominal mass was the presenting symptom. A ten centimeter right lower quadrant mass was found on physical examination. Pelvic ultrasound showed a large cystic mass with an intravenous pyelogram showing bilateral ureteral compression. Upon total abdominal hysterectomy, bilateral salpingo-oophorectomy, and omentectomy, two ovarian masses were found. The right was 30 by 20 centimeters and the left was 10 by 10 centimeters. No implants were evident. Pathologic diagnosis was of a bilateral mucinous borderline tumor. The patient was doing well two years postoperatively.

The final case is a sixty-two year-old (unknown parity) who was admitted with a two month history of intense pelvic cramping. A retroverted uterus and a firm tender mass were present on pelvic examination. Abdominal roentgenogram revealed a mass above the bladder. Two cystic masses were seen on the pelvic ultrasound. Cystocopy was performed with no evidence of bladder invasion. Total abdominal hysterectomy, bilateral salpingo-oophorectomy, and omentectomy were performed finding large hemorrhagic cysts on both sides. Diagnosis was papillary borderline cystadenoma. The patient had no evidence of disease four and one-half years postoperatively.

Discussion

These tumors have come to be classified solely on histologic characteristics and have been defined as neoplasms exhibiting a degree of cellular proliferation, greater than that seen in benign forms, but showing no destructive invasion of the stromal component. [1] Grossly, borderline serous tumors are similar to benign serous cystadenomas, but have a more prominent papillary component. [2] About 15% have extraovarian extensions or "implants" in the abdominal viscera, or omentum which

Table 2

Year	*Serous Cystadeno Carcinoma*	*Mucinous Cystadeno Carcinoma*	*Serous Borderline Malignancy*	*Mucinous Tumor Borderline Malignancy*	*Adenocarcinoma and Undifferentiated Carcinoma*	*Endometrioid Carcinoma*	*Granulosa Cell Tumor*	*Terato-Carcinoma*	*Endodermal Sinus Tumor*	*Mesonephric Tumor*
84	3			1	3					
83			1		4		1			
82	2	1			3		1		1	
81		1	1	1	1					
80	1					1				
79					1	1				
78					1			1		1
77	1	1			1	4				
76		2				1		1		
75	2	1			4					
Total	9	6	2	2	18	7	2	2	1	1

show histologic changes resembling the epithelial proliferation seen in the parent tumors. Even in the presence of these implants a relatively benign clinical course is the norm.[3]

Mucinous borderline tumors grossly show multiocular, cystic areas with a smooth outer surface.[1] Necrosis, hemorrhage and solid areas are noted only occasionally.[2] Extension beyond the ovary is seen in about 15% in the form of pseudomyxoma peritonei. In some mucinous tumors dissolution of the cyst epithelium occurs with pooling and tracking of mucin into the tumor stroma, and then into the peritoneal cavity.[3] This occurs in about one-fourth of cases, but is not regarded as invasion, and does not alter classification.[2] These are more commonly bilateral.

For classification as a borderline tumor a neoplasm requires at least two of the following: epithelial budding; multilayering of the epithelium; increased mitotic activity; or nuclear atypia.[4] In our four cases (see Table 4) these tumors were described as having all four of the necessary microscopic findings.

Serious borderline cystadenomas have a ten-year survival rate of about 75% compared to 13% for frank carcinomas.[3] Those with peritoneal implants have a somewhat poorer survival. Series have shown between 68%-87% ten-year survival rate in borderline mucinous tumors compared to about 34% for frank carcinomas.[3] Study of these tumors is much more problematic due to the difficulty in ascertaining stromal invasion.

It is currently recommended that in a young patient with unilateral disease, unilateral salpingo-oophorectomy is appropriate initial management.[2, 3] After the childbearing age, pelvic clearance should be performed. Total abdominal hysterectomy, bilateral salpingo-oophorectomy, and omentectomy is recommended in older patients, in those with bilateral tumors, or where peritoneal lesions are found.[2] Those patients having peritoneal deposits should be followed closely.

The importance of recognizing these tumors is in differentiation from ovarian carcinomas. Prognosis is much better in these borderline tumors and management may be more conservative. These tumors occur more often in women of childbearing years where retention of reproductive organs without compromising survival is an important consideration. Careful inspection by the surgeon at the time of operation and close follow-up should provide clear guidelines for the definitive treatment of these tumors.

Table 3

Case	*Age at Diagnosis*	*Diagnosis*	*Surgical Procedure*	*Date of Surgery*
1	55	Borderline mucinous cystadenoma	TAH-BSO Partial omentectomy	6-84
2	35	Papillary borderline serous	D and C, left oophorectomy, right ovary wedge resection, peritoneal washings	11-83
3	30	Bilateral borderline mucinous cystadenoma	TAH-BSO omentectomy	4-81
4	62	Serous papillary borderline cystadenoma	Cystoscopy, TAH-BSO, omentectomy	5-80

Table 4

Case		*Epithelial Budding*	*Multilayered Epithelium*	*Increased Mitotic Activity*	*Nuclear Atypia*
1		+	+	+	+
2		+	+	+	+
3	*Right*	+	+	+	+
	Left	+	+	+	+
4		+	+	+	+

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Radiation Therapy of Carcinoma of the Prostate

Experience at a Community Hospital

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ABSTRACT–External radiation therapy at New Britain General Hospital has been effective in the treatment of carcinoma of the prostate over a twelve year period. Actuarial survival of 91% at five years and 72% at ten years has been achieved without significant morbidity. These results compare favorably with the Stanford experience over a 28-year period.

Definitive external beam irradiation of prostatic cancer in the United States began at Stanford University in the mid-1950's. The Stanford experience has demonstrated that long-term survival can be achieved after appropriate prostatic irradiation. [1-3] The most recent data presented by Bagshaw[4] involves 477 patients with disease limited to the prostate (nominal Stages A and B) and 402 patients with extracapsular extension (nominal Stage C) treated from 1956 to 1983. This series shows actuarial survivals of 81% at five years, 59% at 10 years, and 36% at 15 years for those with disease limited to the prostate. It shows actuarial survivals of 62% at five years, 36% at 10 years, and 18% at 15 years for those with extracapsular extension.

This report summarizes the results of 81 prostate patients treated at a community hospital between 1973 and 1985 with external beam radiation therapy. Within this group, 78 patients had disease limited to the prostate, and three had extracapsular extension.

Technique

A four-field isocentric technique was used to treat the prostate and pelvic nodes to a dose of 4000 rad. A smaller field was used to deliver an additional 2500 rad to the prostate with a bilateral arc technique. Fifteen patients were treated with a cobalt-60 unit, and 66 patients were treated with a Varian Clinac-4 linear accelerator. Tumor localization was performed using orthogonal radiographs. Computed Tomography (CT) scans were used for localization after 1981. Dose distributions were accomplished using a computerized treatment planning system.

Results

The actuarial survival for this series of patients is 91% at five years and 72% at ten years (Figure 1). Eight patients have died, all within the 2nd and 7th years following treatment. Ten patients are currently alive beyond the 7th year.

Seven of the patients had local recurrence. Two of these have died. The other six who have died had evidence of distant metastases.

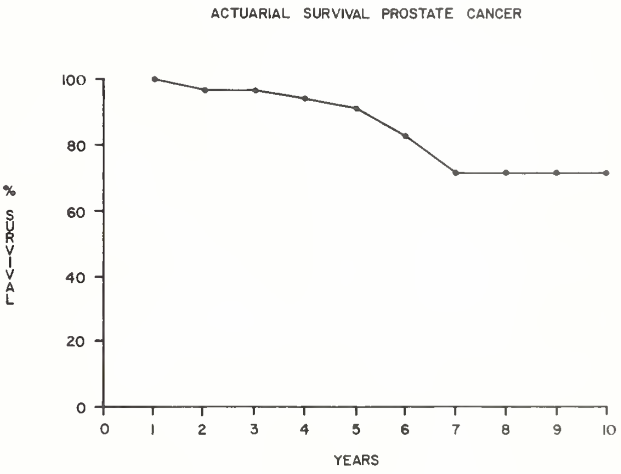

Figure 1

Acute morbidity for this series of patients was limited to some diarrhea and some urinary symptoms. These symptoms were not considered major in any of the patients. One patient who was treated with 7000 rad on the cobalt-60 unit developed radiation cystitis which resulted in a total cystectomy. He has survived eight years free of disease. Two patients developed hemorrhagic cystitis which responded to conservative measures. There have been no problems with ongoing urinary symptoms. Sexual prowess before and after treatment has not been evaluated.

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BEHIND THE FACE OF HYPERTENSION

Important Advances in Clinical Medicine

Epitomes of Progress—Preventive Medicine and Public Health

The Scientific Board of the California Medical Association presents the following inventory of items of progress in preventive medicine and public health. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in preventive medicine and public health that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Preventive Medicine and Public Health of the California Medical Association and the summaries were prepared under its direction.

Preventing Influenza in the Elderly

Studies have consistently shown that the elderly and those with certain medical conditions are at the highest risk for morbidity and mortality due to influenza virus infections. Influenza and pneumonia remain the fourth leading cause of death in the elderly. The US Public Health Service's Advisory Committee on Immunization Practices recommends that the elderly and other high-risk groups be vaccinated annually against influenza infection. However, the recommendation has been based primarily on extrapolated efficacy data from younger populations, rather than on data directly documenting vaccine efficacy in elderly populations. Also, the recommendation is generally not followed. In national surveys, only about 20% of high-risk patients are vaccinated annually.

Vaccination of nursing home elderly patients may be particularly important. Epidemics of influenza in nursing homes are associated with high morbidity and mortality, and more data have accumulated regarding vaccine efficacy in this setting. In a recent study of the influenza A epidemic in Michigan between December 1982 and March 1983, vaccinated nursing home residents were less likely to become ill, have development of pneumonia, be admitted to hospital or die. Although the reported vaccine efficacy of 28% to 37% inferred from attack rates was considerably lower than usual estimates of efficacy, these results suggest that, at least in nursing home patients, influenza vaccination may attenuate infection even if it does not prevent it. These data also show significant noncompliance. Even though physicians routinely ordered flu shots for the Michigan nursing home patients, 46% of patients were not vaccinated because they refused or because relatives did not give consent.

In a recent longitudinal, prospective study of attitudinal risk factors for noncompliance, patients' attitudes about influenza vaccine effectiveness, vaccine side effects and their physicians' opinion of influenza vaccination strongly predicted compliance with flu shots in two consecutive flu seasons. Overall, patients' behavior regarding flu vaccination was consistent during the two flu seasons. Compliance changed in 10% to 15% of patients, primarily associated with changes in attitudes about side effects of influenza vaccine. A combination of physician counseling and efforts to identify and contact high-risk patients may improve compliance. Annually mailing letter reminders combined with physician counseling have gradually increased a clinic's vaccination rates to more than 70%.

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Clinical Basis for Treating Presumptive Chlamydial Infection

Chlamydia trachomatis is our most common sexually transmitted pathogen and is responsible for an estimated 3 million cases of infection annually in the United States. The most common presentation is nongonococcal urethritis in men, but the most important consequences of chlamydial infection—acute salpingitis, tubal factor infertility and probably ectopic pregnancy—occur in women. *C trachomatis* also causes inclusion conjunctivitis and pneumonia in young infants.

The accurate diagnosis of chlamydial infection, not available in most clinical settings, depends on expensive tissue culture isolation procedures. Because chlamydial infections occur at high rates in certain clinical conditions, the Centers for Disease Control recommend antichlamydial therapy—500 mg of tetracycline four times a day for seven days—for persons with those findings and for their sex partners.

Heterosexual patients with gonorrhea and their partners should be treated for chlamydial infection because about 20% of men and 40% of women with gonococcal infections also have chlamydial infection.

Other conditions that call for presumptive therapy in men are nongonococcal urethritis and epididymo-orchitis; treatment should be given for at least ten days. For women, muco-purulent endocervicitis or acute salpingitis call for antichlamydial therapy, salpingitis requiring multiple drug therapy to cover all pathogens. Again, therapy should be given for at least ten days.

Infants with inclusion conjunctivitis or *Chlamydia* pneumonia and their parents should also be treated. Erythromycin is the drug of choice for treating infants and pregnant women.

Chlamydial cultures should be used preferentially for testing persons who would not be treated on a presumptive basis. Groups benefiting from screening include young, particularly adolescent, sexually active women and pregnant women in socioeconomic circumstances that suggest a high risk for sexually transmitted disease.

Recently introduced nonculture methods may make chlamydial diagnosis more widely available and less expensive. More experience is needed, however, to assess the performance profiles of these tests to best determine how they can be used. Because all nonculture methods have some false-positive results, they should not be used for screening in low prevalence settings.

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Polysaccharide Vaccine for Preventing *Hemophilus influenzae* Type b Disease

A polysaccharide vaccine for preventing invasive diseases caused by *Hemophilus influenzae* type b (Hib) was recently licensed by the US Food and Drug Administration (Hemophilus b polysaccharide vaccine; b-Capsa I, Mead Johnson).* *H influenzae* type b is the leading cause of bacterial meningitis in the United States and an important cause of other systemic illness. An estimated 20,000 cases of *H influenzae* type b occur annually; 1 out of 200 children will have an episode of invasive *H influenzae* type b before reaching their fifth birthday. In spite of antibiotic therapy, 5% to 10% of patients die and 25% of the patients with meningitis who survive will have neurologic sequelae. The incidence of this disease is highest in young children and declines rapidly with increasing age. In two recent studies, there was a significantly increased risk of primary *H influenzae* type b in children attending day care. Children with asplenia, sickle cell disease, Hodgkin's disease and antibody-deficiency syndromes are also at increased risk of this disease.

The recently licensed Hib vaccine consists of the purified polysaccharide capsule of the organism. Like other capsular polysaccharide vaccines (meningococcal and pneumococcal vaccine), the vaccine produces minimal adverse reactions, but it is poorly immunogenic in young children. The vaccine elicits an antibody response likely to be protective in children 18 to 20 months old; geometric mean antibody titers rise with age. A prelicensure clinical trial in Finland showed 90% efficacy in children 18 to 71 months of age, but no efficacy in children younger than 18 months. There were insufficient numbers in each age category in this study to assess efficacy in children 18 to 23 months of age, although no cases occurred in the four-year follow-up of 4,000 children in this age group who received the vaccine. An efficacy trial is currently under way on a new Hib vaccine consisting of a covalently linked polysaccharide protein that may be efficacious in young children; if effective, this vaccine could be available as early as 1988. In the interim, the 25% to 35% of cases of invasive *H influenzae* type b in older children is potentially preventable by using the polysaccharide vaccine. The US Public Health Service Advisory Committee on Immunization Practices therefore recommends the universal use of the vaccine at 24 months of age; vaccination at 18 months is suggested for children at high risk of disease, including those in day care. Additional information regarding the duration of antibody response is needed to define the possible need for and timing of a second dose of vaccine in children vaccinated at 18 to 23 months. The vaccine is not recommended for children younger than 18 months. Immunizing children older than 24 months who have not yet received the type b vaccine should be based on their risk of disease. The vaccine is not recommended for preventing otitis media or upper respiratory tract disease, since these are due predominantly to unencapsulated *H influenzae*.

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*Use of the trade name does not constitute endorsement by the US Public Health Service.

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Preventing Low Birth Weight

Infants weighing 2,501 grams or less at birth are 40 times more likely to die during the first four weeks of life than are infants with a normal birth weight, and they have increased risks for major and minor handicapping conditions, as well. Unfortunately, the decline between 1965 and 1980 in the infant mortality rate in the United States (from 24.7 to 13.1 per 1,000 live births) was not accompanied by a parallel decline in the rate of low-birth-weight infants. Lower infant mortality is due primarily to improved survival of low-birth-weight infants, involving high-cost neonatal intensive care and carrying uncertain prospects for childhood development.

According to a new report from the Institute of Medicine, sustaining the decline in infant mortality will require major actions to prevent low birth weights, emphasizing better maternal health, good nutrition for pregnant women and systematic and early prenatal care. During the early 1980s, federal support for such low-cost, high-yield programs has been limited. An analysis using census tract income data and birth tapes from the state of Washington has shown that the proportion of births receiving no or late prenatal care, the proportion of low-birth-weight infants and the prevalence of maternal anemia all increased in the low-income populations. Such findings have given renewed impetus to state-level initiatives to provide Medicaid eligibility, to enhance primary care and case management and to assure nutritional supplementation for poor pregnant women.

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Preventing Osteoporosis

Loss of bone mass is a universal phenomenon of aging. Clinically significant osteoporosis—that associated with fracture in the absense of major trauma—is primarily a disease of postmenopausal white women. Men and black women are at much lower risk. In the United States, one in four white women will have an osteoporotic spinal fracture by the age of 60 and by the age of 90, one in five will have an osteoporotic hip fracture. One third of patients die within a year of an osteoporotic hip fracture and another third suffer chronic disability.

In addition to age, gender and race, other probable risk factors for osteoporosis include height, leanness, cigarette smoking, lack of weight-bearing exercise and low calcium intake. General recommendations to prevent or delay osteoporosis for both men and women of all races include not smoking, moderate exercise (extreme exercise such as marathon running may cause osteoporosis in some young women) and increased calcium and vitamin D intake.

For postmenopausal women, the currently recommended daily calcium intake to retard osteoporosis is 1.5 grams a day. This dose can be accomplished by drinking five 8-oz glasses of milk (preferably low fat or skim) or by the use of calcium supplements (preferably calcium carbonate). Milk has the advantage of being an excellent source of vitamin D. Bone meal products should be avoided because they may contain contaminants such as lead. Adequate calcium intake should begin early in life because it may lead to a greater bone mass, thus delaying the development of clinically significant osteoporosis in later years. Calcium supplements have been shown to improve calcium balance and retard bone loss when begun as late as eight years after menopause, however.

For postmenopausal women the single most effective preventive measure is estrogen-replacement therapy. Numerous clinical trials, primarily in women who have had oophorectomies, have shown that bone loss can be prevented with supplemental estrogen. The minimum effective dose of conjugated equine estrogen, the most commonly prescribed noncontraceptive estrogen in the United States, is 0.625 mg per day. Optimal results are achieved when estrogen is begun within a year of menopause, but cessation of bone loss and some increase in bone density may be achieved when estrogen therapy is begun six or more years after menopause. Bone loss resumes at its previous rate when estrogen is discontinued, so long-term use is necessary. The osteotrophic effects of estrogen are not impaired when a progestin is added, a practice frequently followed to reduce the risk of estrogen-associated endometrial cancer. Less is known about the long-term risks of progestin than estrogen alone, however.

There is mounting evidence that estrogen used alone may reduce ischemic heart disease mortality, possibly mediated by estrogen-induced increases in high-density-lipoprotein cholesterol. This effect is lost or modified by adding a progestin. There are no long-term studies that compare the effects of estrogen-progestin on death or cardiovascular disease risk in treated and untreated postmenopausal women. If the use of only estrogen reduces ischemic heart disease risk, this health benefit would be much greater than the risk of endometrial cancer, which is far less common and less lethal than heart disease. In that case, the use of estrogen only would be preferable to the estrogen-progestin combination.

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Toxic Materials and Practicing Physicians

Physicians are increasingly more likely to encounter patients who are ill from exposure to a known toxic material, ill from suspected exposure to a toxic material (either the toxicity, the exposure or both may be unknown) or not ill but concerned about an exposure. These situations can be trying for both patient and physician for many reasons. First, the scope of the toxic materials issue is wide and getting wider all the time ("doesn't everything cause cancer, Doctor?"). Second, current theory suggests that carcinogens do not have thresholds below which the probability of disease is zero, though it may be miniscule. Third, our hindsight concerning exposure conditions once thought to be trivial has made us very cautious about giving reassurance in the face of great uncertainty (such as the swine flu vaccine).

The scope of the issue ranges all the way from occupational exposure to cyanide (high dose, known great toxicity) or asbestos (high dose, known carcinogen), to consuming wild ducks shot near Kesterson National Wildlife Refuge (central California) that may have elevated residues of selenium (low-to-zero dose, uncertain toxicity), to simply residing in a neighborhood within a couple of miles of a hazardous waste site (unknown dose, unknown agents, unknown toxicity). With this wide a range of known and unknown possibilities and unknowables, patients want help dealing with their perceptions of health with respect to toxic substances. In addition, medical professionals have specific occupational exposures of concern to them (nurses and pharmacists making up and administering cancer chemotherapeutic agents, x-ray personnel, operating room staff exposed to ethylene oxide sterilizing gas and anesthetics and so forth).

The history of modern medical science teaches epidemiologists that the first clue to previously unknown agent-host-environment relationships often comes from an alert and curious clinician who sees a case in a novel light and shares these thoughts with others who can help find additional examples and pursue the matter further. This process can be facilitated when those of us responsible for studying these problems in the public health community make ourselves available to share what information we have and help clinicians provide responses to patients who are anxious, ill or both. A call to a county health department is always in order. At the state level, such assistance is usually available from the departments of health (drinking water, hazardous waste, food and drug contaminants, pesticides, synthetic chemicals, carcinogens and teratogens, general environmental and occupational exposures, indoor air contaminants, metals and the like); agriculture (agricultural chemicals, toxic plants); industrial relations (occupational exposures and conditions); the air quality office (constituents of air pollution in various locations); the water quality office (constituents of ground and surface water pollution in various locations), and elsewhere. In California, the first call might best be directed to the new Tox-Info Center, a joint effort of the California Department of Health Services and the University of California at San Francisco (hotline 800-233-3360 is toll-free in California).

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Cancer In Situ of the Uterus and Cigarette Smoking

Recommendations for the frequency of Papanicolaou tests have been based on the assumption that cancer of the uterine cervix is a venereally transmitted disease. Young women who are sexually active are advised to have a smear taken regularly. Over the past eight years several studies have raised the possibility that cigarette smoking is an independent risk factor for cervical cancer and is associated with a substantially higher risk than seen in women with multiple sexual partners.

In 1977 Winkelstein and co-workers pointed out the association seen between cigarette smoking and cancer of the uterine cervix in the data collected by the National Cancer Institute between 1969 and 1971. They suggested further research. Since that time, four carefully designed case-control studies testing this hypothesis have been completed. All have found that cigarette smoking is a risk factor for cancer of the uterine cervix independent of sexual activity. The risk was estimated at between 8 and 17 times greater, and has been found for dysplasias of the cervix as well as in situ carcinoma. Winkelstein and associates reviewed the evidence again in 1984 and concluded that there likely was a causal connection between smoking and cervical neoplasia.

In 1985 Sasson and colleagues showed the presence of nicotine and cotinine in the vaginal fluid of cigarette smokers. The uterine cervix of a smoker is thus bathed in the metabolic products of cigarette smoking, much like the epithelial lining of the urinary bladder, but at higher concentrations.

Based on these data, physicians must view cigarette smoking as an independent risk factor when making recommendations about the frequency of Pap smears and should recommend careful surveillance regardless of a woman's sexual exposures.

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Milk-Borne Diseases

Since the advent at the turn of the century of pasteurization of nearly all market milk in this country, large-scale outbreaks of milk-borne diseases have been rare. Where disease problems still occur, these have been primarily associated with raw (unpasteurized) milk and, on rare occasions, with pasteurized milk. A vivid example of this latter situation was documented in Chicago in the summer of 1984 and again in March and April 1985 when thousands of consumers of pasteurized low-fat milk produced by a single dairy were infected with *Salmonella typhimurium.* The findings suggest that the pasteurized milk was inadvertently mixed with raw milk. This underscores the documented hazard of raw milk as a source of human pathogens. Virtually all other episodes of disease problems associated with "pasteurized" milk have been found, ultimately, to be due to postpasteurization contamination or inadequate pasteurization.

Listeriosis is a disease that has been associated with pasteurized and, more recently, in the Jalisco cheese outbreak in California, with inadequately pasteurized or postpasteurized contaminated milk. A possible explanation as to why *Listeria* can still be a problem with pasteurized milk is that leucocytes (which are in milk, especially from infected cows) may contain and thereby protect *Listeria* organisms from inactivation by routine pasteurization procedures. Obviously, if some *Listeria* can persist despite routine pasteurization procedures, raw milk must pose an even greater risk from this bacterial pathogen.

The major disease problems associated with milk in this country, however, are those of salmonellosis and campylobacteriosis; these continue to be linked to raw milk, including certified raw milk. In addition, other diseases linked to raw-milk ingestion include brucellosis, colibacillosis, corynebacteriosis, staphylococcal poisoning, streptococcal infection and tuberculosis. A newly recognized problem that has been linked to the consumption of raw milk is that of "Brainerd diarrhea," a type of diarrhea first reported from Minnesota in 1984. This illness is characterized by the abrupt onset of numerous watery stools (15 to 25 per day) and a pronounced urgency to defecate but few systemic symptoms. Cases of Brainerd diarrhea tend to be persistent and 70% of patients have continued to experience diarrhea a year or more after onset. No etiologic agent has yet been identified.

Health care providers need to be alert to the potential of milk-borne disease, especially when raw milk or raw milk products are consumed. More than 95% of all milk in this country is pasteurized, but more than 95% of all milk-borne outbreaks are due to raw milk.

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Combined Oral Contraceptives and Cancer

Combined oral contraceptives contain an estrogen and a progestogen in each pill taken during a monthly cycle of use. They were first introduced in the United States in 1960, and it has been estimated that as many as 70% of all women of reproductive age in this country have used these products. Because they are used by such a large number of healthy women with alternative methods to prevent unwanted pregnancies, much higher standards for their safety are warranted than for drugs that are used therapeutically by a smaller number of women with illnesses that result in morbidity or mortality if untreated. One area of major concern is whether combined oral contraceptives alter the risk of certain neoplasms, and many epidemiologic studies have been done to address this issue.

These studies are of two types. In prospective studies, of which there are four major ones, a large number of women using various methods of contraception are observed over a period of time and rates of various cancers in users of oral contraceptives are compared with rates in users of other contraceptive methods. In case-control studies, a series of cases of a particular cancer and a comparable disease-free control group are assembled and their prior use of steroid contraceptives contrasted. Scores of both retrospective and prospective studies have been conducted. Although no single study is definitive, and many questions remain unanswered, results from these investigations provide sufficient information to draw tentative conclusions regarding the influence of combined oral contraceptives, as they have been used in the past, on the risk of neoplasms of the breast, ovary, endometrium, cervix and liver.

At least eight studies have shown the risk of epithelial ovarian carcinomas to be reduced in women who have used combined oral contraceptives. The amount of protection increases with the number of years they are taken and may reach a reduction of more than 50% after five years of use. A similar protective effect has been observed for endometrial cancer. These protective effects appear to persist for a number of years after stopping their use.

Combined oral contraceptives have also been shown to reduce the risk for both benign cystic disease and fibroadenomas of the breast. They have not altered the risk of mammary carcinomas. More than a dozen case-control studies and three prospective studies have failed to convincingly show an increased risk in women who have ever used combined oral contraceptives, in long-term users or in women who used oral contraceptives a number of years in the past. The use of oral contraceptives by women at an early age or before their first pregnancy has been associated with an increased risk of breast cancer in some recent studies, but not in others, and this issue is currently a topic of active investigation.

Cervical cancer has been particularly difficult to study because in some cultures women who use oral contraceptives, like women who are at increased risk for this disease, tend to have multiple sexual partners, and it is difficult to separate the effects of this sexual behavior of oral contraceptive users on risk from the actual effect of the contraceptives. Detailed, accurate sexual histories are required, and these are difficult to obtain. Studies of cases of carinoma in situ in relation to oral contraceptives have yielded inconsistent results, probably in part because the sexual behavior of the study subjects was not adequately considered. However, recent results from three prospective studies and one case-control study have shown an increase in the risk of invasive cervical cancer in users of combined oral contraceptives, suggesting that these products may enhance the progress of preexisting cervical lesions. Further investigations of this issue are under way. Although it cannot be concluded with certainty that oral contraceptives enhance the risk for invasive carcinoma of the cervix, users of these products, like other sexually active women, should have periodic Papanicolaou tests.

Hepatic cell adenomas are benign but highly vascular, can rupture and occasionally cause death. The risk of these tumors is increased in users of combined oral contraceptives, but fortunately this is an extremely rare phenomenon. There is no good evidence that the risk of hepatic cell carcinoma is increased by using oral contraceptives, although this is a topic currently under investigation.

Other neoplasms, including melanomas, pituitary adenomas and carcinomas of the thyroid and gallbladder, have been investigated, but oral contraceptives have not been shown to enhance their risk. Formal studies are continuing to provide the information needed to develop an accurate risk-benefit assessment of combined oral contraceptives. To date, they appear to be remarkably safe products and may prevent more cancers than they cause.

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The Lung Cancer Epidemic

Public health programs were developed to solve serious community health problems, and epidemics have always been among the most pressing of those. In place of the vanished tuberculosis epidemic of the last century is the current lung cancer epidemic. This disease is not directly transmissible from one person to the next except insofar as smoking behavior, its major recognized causal agent, is a model for mimicry by one's companions.

Lung cancer deaths have now surpassed breast cancer deaths as the leading cancer mortality in women. This increase is unquestionably the result of an increasing proportion of the female population that smokes. This is particularly true and problematic with teenaged women.

Despite the protestations of the tobacco industry, cigarette smoking is recognized as the most important cause of lung cancer, though it acts as a tumor promoter rather than a tumor initiator. Stopping smoking has been shown to diminish the risk of lung cancer mortality as the period of abstinence lengthens after the first year.

In conjunction with smoking, workplace exposures to carcinogens (asbestos, bischloromethyl ether, chromates, nickel carbonyl and so forth) are important causes of lung cancer. Urban airborne pollutants also contribute to risk but to a much lesser degree. A sequel to the recent wave of home-insulation improvement has been the indoor accumulation of radon gas whose α-emitting daughter products are carcinogenic when inhaled. Though controversial, there is some suggestion that exposure to cigarette smoke may be involved in an increased lung cancer risk for a nonsmoker (passive smoking).

Although in some states the annual increase of cases of lung cancer seems to have peaked, the clearly excessive risks of lung cancer occurrence remain. More effective documentation and control of high-risk circumstances are needed to achieve significant levels of prevention. Each state needs to follow the US Surgeon General's lead, declare lung cancer to be an epidemic and allocate resources for epidemiologic surveillance and control. Prevention is the ultimate form of ethical medical cost control.

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Nonmedicinal Treatment of Hypertension

As a result of increased consumer awareness of the risks of hypertension and increased physician awareness of the benefits of early detection and treatment, primary care clinicians are more frequently encountering persons with mild hypertension (diastolic, 90 to 104 mm of mercury). Rather than immediately prescribing drugs, it may be preferable to negotiate with patients various life-style changes that have been shown to lower blood pressure. The possibility of avoiding medication is a strong incentive for many people, thereby increasing patient compliance.

The nonmedicinal approach to treating hypertension takes into account nutrition, weight, exercise and stress management.

Nutrition

Patients with hypertension need to be educated about avoiding salt and, more important, salty foods. Although we now know that not all persons are salt-sensitive, the excessively high average daily American intake of salt, combined with the lack of an accurate means of predicting who is salt-sensitive, justifies this recommendation for all patients with hypertension. Giving patients a handout listing the salt content of various foods saves physicians time and serves as a valuable reference for a patient. If hyperlipidemia is detected, then further nutritional counseling about avoiding high-cholesterol foods (organ and red meats, eggs, whole milk dairy products and shellfish) or high triglyceride foods (sugar, sweets and alcohol) with the help of additional patient handouts or a nutritionist referral would be necessary.

Weight

There is a direct correlation between obesity and hypertension. Although a goal is set to achieve and maintain a realistic body weight, it is surprising how even a small loss of 7 to 9 kg (15 to 20 lb) can lower a mildly elevated blood pressure to an acceptable level. The loss is best achieved slowly as the person adopts a more healthy diet rich in fiber and complex carbohydrates and low in fat and sugar and embarks on a regular exercise program.

Exercise

Daily sustained aerobic exercise results in lower blood pressure, lower serum levels of cholesterol and triglycerides, a slower resting heart rate indicative of a more efficient cardiovascular system, weight loss from both increased caloric expenditure and heightened metabolic rate and lowered stress levels. Recommending books like *Fit or Fat* by Covert Bailey provides a patient with guidelines for the length of time required for various aerobic activities and their desired maximum heart rates based on their general state of health.

Stress Management

Attempts to cope with today's highly technologic, impersonal and frustrating society have caused an elevated blood pressure in many people under high adrenergic stimulation. Because many people have difficulty identifying or acknowledging their stress, this aspect of nonmedical treatment of hypertension may require more in-depth discussion at subsequent visits. Nonetheless, a brief general discussion of how stress raises blood pressure, examples of various stress inducers (such as work, interpersonal relationships, finances) and a list of activities or techniques designed to lower stress are essential. A patient handout is again very helpful, listing such relaxing possibilities as hobbies, aerobic exercise, breathing exercises, biofeedback, meditation, music and reading, among others.

These four nonmedicinal treatments of hypertension should also be used with cases of moderate and severe hypertension. Obviously, people with higher blood pressures require medicinal treatment as well, but early emphasis by physicians about personal habits shows that a patient's life-style has contributed to his or her illness and that moderating harmful habits would greatly enhance the effect of medication, resulting in lowered doses, fewer side effects and cost containment, and give patients a sense of control over their own health.

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Diet and Cancer

Despite advances in treatment, age-adjusted mortality rates of cancer have continued to increase at a rate of about 3% every decade. Data on secular trends in incidence are less reliable, but it is probable that age-adjusted incidence rates are increasing at an even greater rate. Most of the increases can be attributed to cigarette smoking, but many cancers unrelated to smoking (such as colorectal cancer) remain as important causes of death. The number of deaths each year due to colorectal cancer (about 60,000) is second only to lung cancer (about 126,000), and it is the leading cause of cancer death in nonsmokers.

Diet appears to play a role in the risk of colorectal cancer. Burkitt's observation with Trowell, Cleave and others that Africans appeared to be at very low risk for colorectal cancer stimulated others to examine the effect of dietary fiber in case-control studies. Several such studies supported the idea that fiber might reduce the risk of colorectal cancer, whereas others were inconclusive. Graham in upstate New York observed that certain vegetables (broccoli, cabbage and brussels sprouts) were associated with a particularly low risk of colorectal cancer.

We suggested that vitamin D and calcium might reduce the risk of colorectal cancer, based on the strong geographical gradient for colorectal cancer in the United States and throughout the world. In particular, colorectal cancer seemed to occur much more frequently in places distant from the equator than in equatorial regions. This theory stimulated further investigation of the possible role of dietary vitamin D and calcium because a principal effect of latitude is increased synthesis in the skin of vitamin D from cholesterol and increased intestinal uptake of calcium.

In a recent study we examined the risk of colorectal cancer according to dietary intake of calcium and vitamin D in Chicago men. Because the men lived in a place where there is relatively little sunshine, well below the US median for solar energy from ultraviolet light at ground level per day, we speculated that dietary sources of vitamin D would be important.

The results of this study show that men who had the lowest intake of vitamin D and calcium had nearly three times the risk of colorectal cancer as men who had the highest intake. Men with intermediate intakes had an intermediate risk of colorectal cancer.

This finding can be added to the work of Shekelle, Bjelke and others showing a protective effect of the carotenes, vegetable-derived previtamin A, on the risk of lung cancer and that of Graham and others showing protective effects of citrus fruit on cancer of the upper gastrointestinal and respiratory tracts. Another study by Phillips showed a reduced risk of many varieties of cancer in association with a Seventh-Day-Adventist (vegetarian, nonsmoking, non-alcohol-drinking) life-style.

A diet to reduce the risk of cancer would include 2.5 to 3 glasses a day of nonfat milk (or 1,000 mg of calcium and 200 to 400 international units of vitamin D_3 per day for lactose-intolerant persons), yellow and green leafy vegetables at least once a day and citrus fruit or juice daily. Such a diet would also require moderation in the use of alcohol (two or fewer drinks, glasses of wine or bottles of beer per day). Restricting fat intake to no more than 20% to 30% of calories and including a bran muffin or the equivalent in dietary fiber every two days would likewise be prudent.

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Hyperlipidemia and Preventing Coronary Heart Disease

The association between hyperlipidemia, especially high low-density-lipoprotein cholesterol, and the incidence of coronary heart disease is a consistent finding in most, if not all, prospective population studies. Indeed, the observed association meets the established scientific criteria for causation and poses two important questions for clinicians. The first question is whether a blood cholesterol-lowering regimen should become a routine part of a practitioner's efforts at prevention. The second question, more strategic than conceptual, is what should be the target population for such a regimen?

Clinical trials on secondary prevention of coronary heart disease—that is, preventing death following acute myocardial infarction—have failed to show a beneficial effect of reducing the blood cholesterol level by dietary means, cholesterol-lowering drugs or both. Thus, in regard to secondary prevention of coronary heart disease, the first question cannot be answered in the affirmative. This makes the second question moot.

As for primary prevention—that is, preventing disease before it strikes—there is evidence that lowering blood cholesterol levels could be beneficial in some persons. Results of a recently completed trial in the Lipid Research Clinical Centers showed that the combination of a prudent dietary regimen and a cholesterol-lowering drug, such as cholestyramine, reduced the incidence of fatal and nonfatal coronary heart disease in men with average blood cholesterol levels of 260 mg per dl and above. Thus, the answer to the first question for primary prevention of coronary heart disease is a qualified yes. This leaves the issue of the target population for prevention open for debate.

There are two models in practice for preventing coronary heart disease. One is a community model in which the target population is the total community. The desired program is aimed at the general population regardless of the level of risk among persons within that population. The other is a medical model of prevention in which the target population consists of persons at high risk who are identified in advance and the desired prevention program—that is, the blood cholesterol-lowering regimen—is targeted at them directly, under medical supervision.

The evidence on the efficacy of a cholesterol-lowering regimen for primary prevention of coronary heart disease is supportive, at best, of a prevention program only under a medical model. Physicians have a unique opportunity to primarily prevent coronary heart disease in their practices by identifying persons with high levels of blood cholesterol (260 mg per dl and above), especially when other risk factors such as hypertension, obesity and cigarette smoking are present, and intervening according to a medical model of prevention under their supervision.

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Preventing Falls in Elderly Persons

Falls in the elderly are a prevalent cause of injuries and an important cause of morbidity and mortality. The cumulative yearly incidence of falls in elderly populations may be 30% to 40%, with 8% to 40% of falls resulting in fractures and 3% of falls resulting in hospital admission. Only half of the elderly patients admitted to hospital as a result of falls are alive one year later.

Primary prevention of falls includes removing hazards in the home. Standard environmental hazards are loose rugs, extension cords, slick bathtubs, stairs and poor lighting. Ambient temperature may be a hazard, as thin or undernourished elderly patients may fall due to lack of coordination resulting from hyperthermia. Thin elderly women with hip fractures have lower body temperatures on admission to hospital than do well-nourished elderly women with hip fractures.

Secondary prevention of falls—that is, preventing their recurrence—depends partly on a clinical examination to search for reversible intrinsic causes. There is no validated screening protocol for falls available, and the differential diagnosis of falls is extensive. A prudent physician would search first for risk factors that merit treatment irrespective of their association with falls, such as visual problems, foot problems, drug toxicity, cardiac arrhythmias, seizure disorders and muscle weakness due to thyroid disease. Intervention to modify other risk factors, such as physical therapy for abnormal gait or a cane for abnormal balance, may be appropriate. At present, however, few data exist documenting the efficacy of risk-factor screening or modification in preventing falls.

More data have accumulated that falls are related to declining physical function. In one study, controlling for functional state eliminated the association of falls with age. In a study of predictors of falls in women with Alzheimer's disease who were in an institution, falls were more closely related to physical decline than mental decline. Hand strength, which correlates with overall body strength, is a predictor of falls and a predictor of complications from an operation for hip fracture. Muscle biopsies at the time of surgical procedure in patients with hip fractures show more leg muscle atrophy than is present in the general population.

A careful clinical examination of patients who fall seems reasonable. Due to the large number of causes for falls and the relationship of falls with physical function, a fall may be a sentinel event for the onset of a disease or of a decline in physical function. Presumably, interventions to prevent falls and to prevent further physical decline are more effective if initiated early. Exercise may have a role in the primary prevention of injury due to falls, as studies show that exercise in the elderly can maintain or increase bone mass as well as increase muscular strength and endurance.

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Disease Outbreaks in Day-Care Centers

The increasing proportion of mothers who are working has resulted in an increase in the number and importance of facilities where children can be cared for during the working day. These vary from neighbors who take care of as few as two to four children within their homes as licensed or unlicensed "day-care homes" to licensed day-care centers that take care of a few dozen to a few hundred children. The children may range in age from 3 months to kindergarten level.

Aggregating these children into a common area, with common playthings, provides an ideal opportunity for the spread of infectious agents by direct contact, by fomites and by airborne droplet nuclei. In addition, these children must be fed, either snacks or meals, from kitchens not usually staffed, equipped or designed for the level of food sanitation required for public eating places. Consequently, diseases spread by the fecal-oral route are frequent, especially when non-toilet-trained infants and toddlers are present. The disease of greatest significance is hepatitis A, which was found in one study to have an asymptomatic-to-symptomatic ratio of 22:1 among day-care children younger than 3 years, this in contrast to a ratio of 1:8 among the staff of a day-care facility. Clinical cases occurred in 88% of the households that had a child in the center. Outbreaks of diarrheal disease, especially shigellosis and giardiasis, have occurred frequently; during the first five weeks of enrollment in a day-care center, there is an average diarrheal attack rate of 25%, declining to 10% among those remaining in the center. The spread of colds and fevers due to a wide variety of microorganisms is traditional; these are most frequent among younger children.

Some control measures are obvious. A program of washing the hands of the staff and of the children after possible contamination with fecal material can reduce the incidence of diarrheal disease by about half. A program of administering immunoglobulin when cases of diarrheal disease occurred in a center child or employee or among parents in two families eliminated cases among center personnel and reduced cases in the community by 75%. Rigorous adherence to immunization schedules eliminates the threat of the vaccine-preventable diseases. Day-care center operators or parents are concerned about keeping a sick child out of the centers. Because infections agents have probably already been spread during the late incubation, however, exclusion may only force a parent to seek another place for child care, further spreading the infection. Therefore, consideration should be given to admitting sick children to the day-care center if facilities and personnel are available to permit separating sick from healthy children.

Day-care centers will increase in importance; professional supervision to assure minimal disease transmission is necessary.

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Battered Women: A Concern For the Medical Profession

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ABSTRACT—Battering of women is a common problem involving all racial and socioeconomic groups. Victims frequently seek medical care but physicians often do not recognize or ignore this problem which is seldom discussed in the medical literature. Stimulated by a multidisciplinary conference on battering, a formal program was instituted in The Waterbury Hospital. Development and dissemination of a protocol and high risk criteria for recognition and intervention in battering resulted in a 180% increase in reported incidence within one year. The victims were predominantly young, with 67% under age 31. Most patients, 88%, sought care in the emergency room and 68% sustained injury to the face and/or head. Physicians should be trained to recognize and treat battered women appropriately.

One million and eight hundred thousand women annually are severely battered by their husbands according to a nationally representative survey of 2,143 couples.[1] These figures substantially underrepresent the true magnitude of the problem since the study included only those married or living as couples. A study of courtship violence between college students at a midwestern university revealed at least one abusive incident in 21.2% of the relationships.[2]

The physical, psychological and emotional consequences make abuse of women a major health issue in the United States. Stark and Flitcraft estimate that nationwide 1 million battered women utilize emergency medical services.[3]

Although it has existed with tacit societal approval for centuries, the plight of battered women has received attention for little more than a decade.[4,5] Reliable statistics are difficult to obtain since victims often hesitate to report or admit the abuse because of fear, shame and/or guilt.

In October, 1983, we conducted a Medlar search of the literature. Almost all of the 132 citations were in the sociological or psychiatric literature rather than medical journals although battered women often seek aid from physicians in emergency rooms, ambulatory clinics and private offices.

This article describes a general hospital's newly instituted program to identify and provide services to battered women and those at high risk; and to present patterns which have emerged from analysis of the preliminary data.

Program Development

The Waterbury Hospital, a 505-bed general hospital, is affiliated with the Yale University School of Medicine. Along with a 347-bed general hospital, it provides care to a 13 community urban-suburban-rural population of approximately 240,000.

The stimulus for initiation of the program for battered women was a hospital-wide conference in December 1982, co-sponsored by the Departments of Medicine and Social Work Service. Dr. Anne Flitcraft described a five-year study of over 2,000 women treated for trauma in the Emergency Room at Yale-New Haven Hospital. Evidence of battering was found in approximately 20% of the women.[3] She outlined a three-stage sequential battering syndrome: stage I—women present with injuries in the central anterior regions of the body (face, head, torso); stage II—visits to outpatient medical clinics, often with

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vague complaints; stage III, development of psycho-social sequaele (alcohol, drug addiction, depression, and suicide attempts).[3]

The presentation evoked considerable interest and led to the formation of an Ad Hoc Committee on Battering and Domestic Violence in January, 1983, by the Director of Clinical Services. Membership includes physicians, nurses, administrators, and social workers, from the Departments of Emergency Medicine, Obstetrics and Gynecology, Surgery, Pediatrics, Psychiatry, Social Work, and Quality Assurance.

The committee established the following goals: retrospective review of reports of battering among patients seeking care; development of criteria for recognition of battering; development and dissemination of a protocol for intervention; in-service education for personnel throughout the hospital; accumulation of statistics in a prospective manner; and evaluation and improvement of the delivery of comprehensive care.

Program Implementation

The protocol and High Risk Criteria were developed by a subcommittee comprised of the authors. An immediate referral to the Social Work Service Department is required for any woman with definite or suspected battering. Social workers assess the situation, the safety of patients and children, and facilitate the use of hospital and community resources. During daytime hours, nights, and weekends, the social worker responsible for coverage carries an area wide pager to insure rapid response. Battered women are offered short term follow-up counseling by staff social workers. Polaroid photographs of injuries are taken with patient consent. Overnight shelter for patients and children is provided in the hospital without formal admission. Longer term shelter is usually available in the community.

A confidential central file on the women is maintained in the Social Work Service Department. To facilitate detection of repeat instances of battering patients names are also filed in the Emergency Room, prenatal and ambulatory clinics.

The High Risk Criteria (Table 1) drawn substantially from Dr. Flitcraft's 1982 presentation and her published work,[3] were distributed to emergency room and outpatient clinic personnel and all resident physicians by July 1983.

Provision of in-service training to various hospital personnel, an essential component of the program, began in February 1983. A series of conferences for residents, physicians and staff in the emergency room, prenatal and surgical units were conducted by the social work author. The learning objectives included: an overview of the problem; Dr. Flitcraft's three stage battering syndrome; most likely sites of injury; development of an "index of suspicion"; and interviewing techniques.

Methodology

For this study a battered woman was any woman physically abused by a spouse or intimate partner. Data were collected over a one-year period (March 1, 1983-February 29, 1984) from emergency room, inpatient and outpatient records, and social work notes. The information was gathered by medical or social work staff through unstructured, informal interviews. The State of Connecticut requires Emergency Room personnel and

Table 1
HIGH YIELD CRITERIA FOR IDENTIFYING BATTERED WOMEN*

Ob/Gyn

Pregnancy increases the likelihood of battering
Incidence of abortion, miscarriage, premature delivery
Pregnancy with injuries/bruises
Sexual dysfunction
Divorce or separation during pregnancy
Persistent gyn complaints—espec. abdominal pain and/or dyspareunia
Suicide attempt during pregnancy

Medicine/Surgery

Frequent visits to many different clinics with vague symptoms:
  Headaches—choking—hyperventilation—asthma—GI upsets—allergic phenomena, chest pain—pelvic pain—back pain—fatigue—sleep disturbance
Clinic findings elusive, non-specific
Symptoms unremitting—chronic somatic complaints
Begins to be labeled—"Crock," "Hysterical," "Hypochondriac," etc.
Requests sleep medication, tranquilizers
Increasing use/abuse of analgesics, tranquilizers, alcohol, drugs
History of repeated emergency room visits for trauma
Does not adhere to treatment plan

Emergency Room

Delay between time of injury and presentation for treatment
Patient's companion reluctant to leave patient during exam
Central trauma to head, face, shoulders, breasts, abdomen
Bilateral injuries
History of injury incompatible with presenting complaint
Familiar excuses to explain injuries—i.e., "I walked into a door."
History of previous traumas
Co-existence of central trauma with pregnancy
  drug abuse
  alcoholism
  depression
  suicide attempts
Alcoholic husband
Triad of trauma, depression and problems with children
Co-existence of trauma with complaints of insomnia, nightmares, anxiety, inability to cope
Hostile reaction to male personnel

Pediatrics

Coexistence of child abuse
Women with children having psychosomatic complaints:
  Headaches, abdominal complaints, peptic ulcer, rheumatoid arthritis, enuresis, asthma, behavioral problems, stuttering, depression, suicidal behavior

Psychiatry

Anxiety state
Inability to cope
Depression
Suicide attempt, particularly if pregnant
Alcoholism
Psychosis
  Paranoia—catatonia—homicidal ideation/rage
Drug abuse

*After Flitcraft[3]

police to report instances of known or suspected battered women to the Department of Human Resources (P.A. 79-321). The data submitted by the hospital for the two years prior to implementation of the study were obtained and used as the baseline.

Results

In the two-year period prior to program implementation 34 and 36 incidences of battering were reported to the Department of Human Resources. During the study period 98 instances were identified, indicating a 180% increase over the baseline. The 98 instances represent 90 women who volunteered or admitted they were battered and named their abusers. Six women were involved in recurrent episodes.

Although the age range of the women was 15-76, 50% were 21-30 and 67% were under 31. Husbands and boyfriends were almost equally represented as the abusers. We noted only seven instances in which children were also abused, and in each the abuser was the male.

White women comprised 73% of the study group with a much smaller representation of black 20%, or Hispanic 7%, women. The usual racial distribution among patients in the emergency room and inpatient visits is white 88%, black 9%, Hispanic 3%. These data indicate a higher incidence of minority representation among the battered women.

The Emergency Room was the source of identification for 88% of the study women. Two or three patients were identified in each of the following areas: prenatal, gynecology, medicine, surgery, and pediatrics.

The most frequent primary sites of injury, the face and head, were noted in over 50% of the study women. In addition, all women in the "multiple injury" category sustained trauma to the face and head as well as significant injury to other parts of the body. A few patients had no identifiable physical injury at the time of presentation and are categorized under "no primary site." (Table 2)

Table 2
PRIMARY SITE OF INJURY N=98

Location/Category	#	%
Face	39	40
Head	18	18
Trunk	7	7
Arms/Hands	7	7
Psychiatric	6	6
Abdomen	4	4
Leg/Toes	3	3
Multiple	10	10
No Site	4	4

When time of presentation was analyzed more battered women sought treatment from 8 a.m.-4 p.m. and on Mondays than at other times. However, the 4 p.m.-midnight-period was also prominently represented.

Discussion

Battering is frequently not recognized by physicians as the cause of injury in women who present for care. Even when recognized, physicians often solely treat the injury and ignore the cause. In an urban, university-community hospital emergency room, physicians recorded battering in 2.8% of the women treated for trauma. When emergency room and past records were reviewed, however, the true incidence appeared to be 25%.[6]

Institution of a formal program for battered women results in a significant increase in diagnoses and affords the opportunity for the provision of essential supportive services. Implementation of a domestic violence program at Brigham & Women's Hospital in Boston also noted a substantial increase in the detection of battered women.[7]

The marked increase in the identification of battered women noted in our study may still underrepresent the full scope of the problem. Lower diagnoses and referral rates were noted from the Medical, Surgical, and Prenatal Services, than would be expected from the literature. Furthermore, our study only included positively identified battered women and did not deal with "probable" or "suggestive" groups.[3]

Our findings and that of others[8,9] indicate that abused women who present to an emergency room comprise a relatively young population. Two studies of women receiving services from shelters substantiate that impression.[10, 11] In addition, Straus's survey of 2,143 couples found violence was highest in those under 30.[1] The higher incidence among younger women may be explained by the following possibilities: the young tend to be more violent and/or have not yet developed appropriate coping mechanisms; older women ultimately extricate themselves from the battering relationship, often when both they and their children are less dependent. Based on our contacts with battered women who have made the decision to leave, the latter explanation appears more likely.

Originally perceived as a problem solely between husbands and wives and termed "wife abuse," battering is far more pervasive. While some studies have found that the abusers in all instances were husbands or cohabitees[1, 12, 13] others have noted that the majority of battered women were single, divorced, or separated.[3, 14] Our own data revealed that a slight majority of the women studied were battered by spouses.

Although the women studied were predominantely white, minority women comprised a larger proportion than would be expected from their user ratio in the emergency room or hospital overall. These variations could denote a difference either in the use of medical providers or the pursuit of treatment. Minority women may not have private physicians or elect not to use them after a violent episode. Conversely, white battered women may request treatment from private physicians or be less likely to seek medical care. Of the minority study women, 13 were clinic patients, and 11 listed private physicians. Six of the women came to the emergency room when their private physicians were less likely to be available.

Although most of the published medical data were obtained in the emergency room, battered women frequently and disproportionately also utilize non-trauma areas.[3] Pre-natal women are victims of violence in alarming numbers. Two studies have reported 25%[15] and 35%[16] of the women interviewed reported violent attacks while pregnant. An increased incidence of miscarriages, abortions, stillbirths and handicapped children attributable to battering during pregnancy has been noted.[6, 12, 13, 16] Intentional blows to the abdomen were reported by three of the six pregnant women in our study. Gelles postulated that battering may be an attempt by the abuser to terminate the pregnancy.[15] One of our women alleged her husband deliberately assaulted her in the abdomen stating he was "going to give her an abortion."

In view of the studies cited above, the low incidence of battering among pregnant women in our program is surprising and suspect. In addition, the number of battered women reported from our medical and surgical services is smaller than would be expected from the literature. Referrals from those services resulted after women had been hospitalized for injuries, some times unrelated to battering, and later discovered to be in abusive relationships.

A two-year retrospective study by the Departments of Surgery and Oto-rhinolargnology at the Huddinge University Hospital in Sweden discovered that 29% of women had injuries caused by battering.[17] As in our study, many instances were discovered only after a few days of hospitalization.

Our findings concur with other studies[3, 8, 16, 17] which found the face and neck to be the most common primary sites of injury. Trauma to the neck is a site which also warrants attention. Although a primary site of trauma in only three women, five women in the multiple injury category also sustained injury by choking. Gayford's study noted 19% of battered women claimed to be victims of strangulation attempts.[12] In addition, Milligan and Anderson reported two patients, age 28 and 34, who presented with strokes as a result of damage to the internal carotid artery caused by battering.[18] They recommended that domestic violence be considered as a possible etiology for carotid artery occlusion in any young woman without obvious cause.

Many battered women present or are evaluated for psychiatric difficulties.[6, 12] Hilberman discovered that 60 women, one-half of all women referred for psychiatric evaluation by the medical staff of a rural clinic over a one-year period, were victims of marital violence.[13] Their complaints centered around physical symptoms or mixed anxiety/depression that the women related to marital problems.[19] Hyperventilation, hysterical paralysis, depression, and anxiety were the presenting psychiatric symptoms of six women studied two of whom were admitted to the medical service.

A high coexistence of wife and child abuse has been noted in the literature. In this area our own low incidence (seven cases) could reflect a tendency to isolate each domestic violence situation as either child abuse or wife battering. Furthermore, there may be a failure to explore the possibility that either parent in a battering situation could be the child abuser. Two studies revealed that, in one-third of the dual battering instances, mothers were the child abusers.[12, 20]

Our data on time of presentation raise some questions. There is a common belief that battering occurs most frequently at night and on weekends.[13] Most of our women studied presented during the daytime hours, while Appleton's study noted one-half of the women presented between 10:00 P.M. to 2:00 A.M. and one-third between 9:00 A.M. to noon.[8] One possibility is that some battered women may delay their request for treatment. Only 10 of the 19 study women who presented on Monday were injured that day.

In conclusion, battering of women is a more pervasive problem than previously acknowledged and should be addressed by the medical profession. Medical schools and teaching hospitals need to expand their curriculum to include the identification and treatment of battered women.

In general hospitals, the recommended approach is institution of a formal program in all treatment areas to facilitate the provision of comprehensive care to battered women. Primary care physicians should be alert to the possibility of battering in their patients. Their diagnostic sensitivity will be increased if they are familiar with the high risk criteria and most likely sites of injury.

Once battering is suspected the most successful approach is direct but sensitive questioning. Since it is never easy to leave a relationship, battered women need supportive services. Hospital personnel should refer abused women to staff social workers, while private physicians must be cognizant of community resources.

Although physicians have played a leadership role in the diagnosis and treatment of victims of child abuse, another form of domestic violence, they have largely failed to demonstrate a similar concern for battered women. Both areas should be within the realm of a physician's professional responsibility and practice.

The authors acknowledge the interest and contributions of the other members of the Committee on Battering and Domestic Violence: B. Berliner, M.D., L. Colella, R.N., E. Hurley, R.N., S. Lieber, M.D., K. Lyons, M.D., N. Shidlovsky, R.N., R. Swaney, M.D., A. Williams, M.S.W. and A. White, M.P.H. A. Williams, Director of Social Work Services, provided monthly statistical data and A. White, Assistant Hospital Administrator, data on E.R. utilization by race. Staff social workers B. Limauro, E. Paine, and D. Poust evaluated many of the patients.

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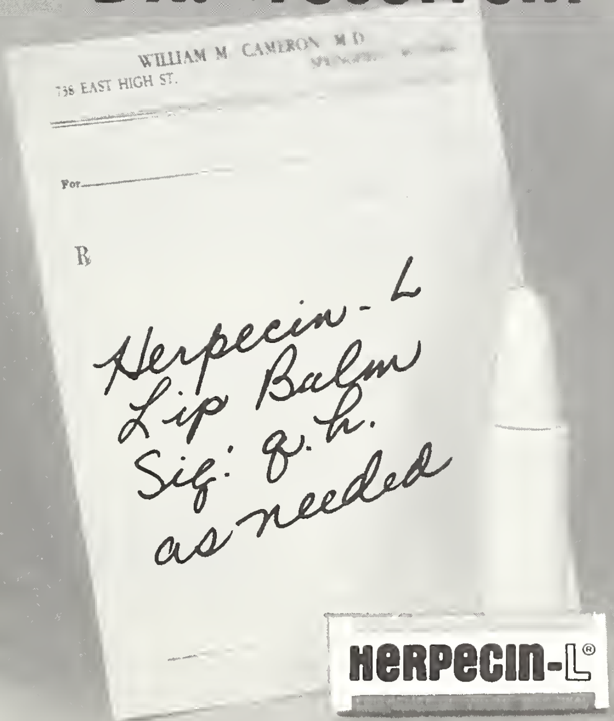
Dx: recurrent herpes labialis



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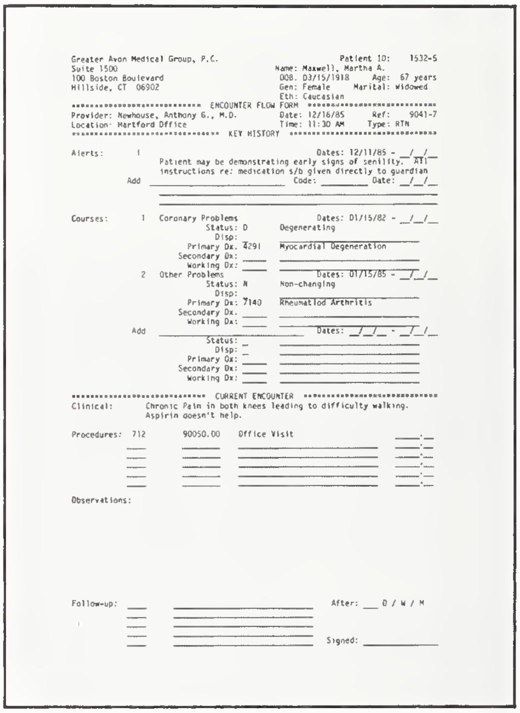

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Greater Avon Medical Group, P.C.                    Patient ID:    1532-5
Suite 1500                                  Name: Maxwell, Martha A.
100 Boston Boulevard                         DOB. 03/15/1918    Age:  67 years
Hillside, CT  06902                          Gen: Female     Marital: Widowed
                                             Eth: Caucasian
**************************** ENCOUNTER FLOW FORM ****************************
Provider: Newhouse, Anthony G., M.D.         Date: 12/16/85      Ref:    9041-7
Location: Hartford Office                    Time: 11:30 AM     Type: RTN
******************************* KEY HISTORY ********************************

Alerts:       1                                   Dates: 12/11/85 - __/__/__
                 Patient may be demonstrating early signs of senility.  All
                 instructions re: medication s/b given directly to guardian
            Add  ____________________________ Code: __________ Date: __/__/__
                 __________________________________________________________
                 __________________________________________________________

Courses:      1  Coronary Problems                Dates: 01/15/82 - __/__/__
                           Status: D      Degenerating
                             Disp:        ______________________________
                      Primary Dx. 4291    Myocardial Degeneration
                    Secondary Dx: _____   ______________________________
                      Working Dx: _____   ______________________________
              2  Other Problems                   Dates: 01/15/85 - __/__/__
                           Status: N      Non-changing
                             Disp:        ______________________________
                      Primary Dx: 7140    Rheumatiod Arthritis
                    Secondary Dx. _____   ______________________________
                      Working Dx: _____   ______________________________
            Add  ______________________________ Dates: __/__/__ - __/__/__
                           Status: _      ______________________________
                             Disp: _      ______________________________
                      Primary Dx: _       ______________________________
                    Secondary Dx: _____   ______________________________
                      Working Dx: _____   ______________________________

**************************** CURRENT ENCOUNTER *****************************
Clinical:       Chronic Pain in both knees leading to difficulty walking.
                Aspirin doesn't help.

Procedures:  712        90050.00   Office Visit
                                                               _____.__
             ___        ________   ____________________________  _____.__
             ___        ________   ____________________________  _____.__
             ___        ________   ____________________________  _____.__
             ___        ________   ____________________________  _____.__
             ___        ________   ____________________________  _____.__

Observations:




Follow-up:   ___     ____________________________     After: ___ D / W / M
             ___     ____________________________
             ___     ____________________________
             ___     ____________________________     Signed: _____________
             ___     ____________________________
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Why Horace Wells—1985?

LEONARD F. MENCZER, D.D.S., M.P.H.

We might first explain "Why Horace Wells," at this time. Interest in our subject was sparked in Hartford in 1984, because it was the 140th anniversary of Wells's discovery that nitrous oxide has sufficient somnific effect to obscure pain during surgical procedures. At the annual joint meeting of the Hartford Medical and Dental Societies (February 1985), the author and Mrs. Diane Neumann (Librarian of the Hartford Medical Society), presented an in-depth retrospective of Wells's years in Hartford (1836-1847) and the 19th Century efforts of prominent Connecticut citizens to gain recognition for Wells's role in the discovery of general anesthesia.

Though others (Long, Morton & Jackson) may claim, and legitimately so, their significant contributions, none so selflessly and methodically went about sharing that knowledge as did Wells. And where Wells during his lifetime never achieved that recognition in the United States, it continues to elude him even in death. This is exemplified by two recently published items. The first, in the public press (The Hartford Courant, December 2, 1984),[1] wherein an article titled "Scientists Gradually Unveiling Mystery of How Anesthetics Work," credits W.G.T. Morton and his ether demonstration, of October 1846 as the origin of Anesthesia. No mention is made of Wells and his work of two years earlier. In the "New England Journal of Medicine" (October 11, 1984,[2]), a background article on the "first" anesthetized patient, Edward Gilbert Abbott, cites only Morton's work.

Again, "why Horace Wells" may be answered in these perspectives:

1. The 150th Anniversary of Wells's discovery will be observed in 1994. A form that American recognition might take would be that of a U.S. Commemorative Postal Stamp with Wells's likeness thereon. Efforts in that direction must certainly be initiated within the next few years, since thousands of such requests are directed annually to the U.S. Postal Service while only a very limited number of such Commemorative Stamps are issued. Some initial efforts in this direction have already been undertaken, but our local committee was informed by the Postal Service that not more than a five-year lead time would be more appropriate.

   Why "American recognition"? Except for Connecticut supporters, Wells does not enjoy a national image, or prominence, for his work in general anesthesia. The French Academy of Science, in January 1848, recognized Wells (not knowing of Long's earlier work). Our own U.S. Congress initiated action in 1854 in the form of a monetary award, but could not decide whether Long, Morton, Jackson or Wells should be so recognized, and, accordingly did not approve any award.
2. Not much about Wells has been "spoken" since 1944, the Centenary Observance of his discovery. Perhaps this decennium may spark interest and research to rediscover, perhaps uncover new material relative to this enigmatic figure.

Wells's Life One of Brilliance-Failure

Wells's career lasted less than 12 chaotic years (1836-1848), during which time he displayed periods of brilliance, failure, ill health, depression and even dual personality.

A comprehensive, sympathetic perspective of Wells was drawn by Archer[3] in 1944, at the time of the centenary observance of Wells's discovery of anesthesia. That profile was partially based on McManus' work, published in 1896,[4] on the occasion of "the Fiftieth Anniversary Celebration and the placing of the Memorial Tablet" on Main Street, in Hartford, at the site of (one of) Wells's offices (180½ Main Street, the office location where Wells had his tooth extracted by John Riggs while under the influence of nitrous oxide).

"How" Archer's involvement and accumulation of Wells's memorabilia is unknown to this writer. Archer was an Associate Professor of Oral Surgery at the University of Pittsburgh at the time, and correspondence[5] with the Librarian of the University brought forth the following reply:

"We also have the private collection of Dr. David Archer, who collected widely in the history of dentistry

---

LEONARD F. MENCZER, D.D.S., M.P.H., Co Curator, Museum of Historical Medicine and Dentistry, Hartford, CT.

> and was extremely interested in the career of Horace Wells. We have several large storage containers which our records show hold hundreds of 19th century dentistry pamphlets which have not been sorted or cataloged. Archer collected many of Wells' publications and publications about Wells, as well as some unusual memorabilia.
>
> "Unfortunately, because of staff shortages . . . there are no plans for a bibliography of the items mentioned . . . . These items are available for examination by all interested parties."

This resource must be further researched.

After months of investigation into Wells's background a different perspective is drawn from that of Archer's. Phrases such as "media cultivator," "oversized ego," "insatiable craving for recognition" emerge, and much of this is evidenced by the newspaper advertising that Wells engaged in. His first ad in Hartford's newspaper (The Connecticut Courant, April 4, 1836) informs the public ("Citizens of Hartford and the adjoining towns") that he has ". . . the new and much improved style of inserting teeth so recently introduced into London and Paris . . . ." And ". . . Dr. Wells would avoid boasting of his own skill, or derogating that of others— . . . ." That was followed a week later (the Connecticut Courant being a weekly newspaper) with a short notice indicating Wells's location; this continued to appear weekly for 17 issues.

Wells's next advertisement (October 28, 1837)[8] tells the public that ". . . he has invented a set of instruments for FILLING TEETH, which by their construction entirely supercede [sic] those in common use." It is worth noting that Wells was all of 22 years of age at this time. This advertisement continued weekly for the remainder of 1837, all of 1838 into early 1839, at which time we find another advertisement citing a new office location and "Reference,"[9] the names of seven area physicians and two laymen, presumably attesting to Wells's character and skill; and this advertisement continued weekly throughout 1839 into early 1840.

Whereas it was customary for professionals to advertise their skills, no one, as noted in the Hartford newspapers, engaged in that practice to the extent that Wells did. Curiously, after a century with no professional advertising, we currently find the past repeating itself in the media.

The invention of a set of instruments for filling teeth was, in all probability, a valid advertisement since Wells was known to have a fertile, active mind and did, in fact, apply for a patent for a "Coal-Sifter (1839)" and later obtained a patent for a "showerbath" (1846)."

Wells's advertising continued almost weekly with one type advertisement or another throughout the years he spent in Hartford 1836-1847. On October 8, 1842[10] his advertisement is addressed to "Those who have charge of children with teeth growing irregular . . ." "to experience his new dental Regulator . . . ." Then on February 11, 1843,[11] Wells's advertisement tells us that he "received the prize of One Hundred Dollars which was publicly offered in Hartford for the best work in dentistry." This appeared weekly for 51 issues of the Connecticut Courant. Unfortunately, no mention of it is made in any of the literature nor has anything so far been uncovered from a review of this newspaper source.

By 1837, a second Hartford newspaper was published, The Hartford Daily Courant, the first issue being September 12, 1837. This resource is yet to be researched on a day to day basis to determine if other advertisements were taken out that otherwise do not appear in the Weekly Connecticut Courant.

In 1838, Case, Tiffany & Company, of Pearl Street, Hartford, printed a small text of Wells's titled "*An Essay on Teeth*, Comprising a Brief Description of Their Formation, Diseases and Proper Treatment." This effort is worth noting as further indication of Wells's "energetic brilliance"; yet, in perspective, the volume is of little consequence when compared to S.S. Fitch's, *A System of Dental Surgery*,[13] published in 1835. The latter is 551 pages in length and cites in excess of 300 author references from the late 16th Century to the time of Fitch's writing.

Wells's erratic nature and possible mental instability might be more clearly drawn by the following citations: Wells, through his first newspaper notice (April 4, 1836)[6] informs us that his office location is "in Main Street, nearly opposite the Connecticut Hotel, 2d door from State Street." The October 28, 1837, advertisement[8] lists his address as 162½ Main Street; then three advertisements appeared in quick succession, two appearing simultaneously,[14] one indicating ". . . to remove from Hartford to a warm climate in consequence of ill health, ..." The second indicating that "Dr. Wells, has removed to Boston." And the third having "resumed his practice on the ninth of May" (1841); the location is given at "No. 8 Asylum Street . . . ." On April 5, 1845 an advertisement appears that John Braddock, Surgeon Dentist has "taken the office recently occupied by Dr. H. Wells, No. 180 Main street, ..."; when Wells occupied those quarters is as yet unknown. This advertisement is followed by one of Wells's (August 3, 1845),[16] indicating that he is located at "No. 14 Asylum street" and will resume his professional business . . . ." The following September (September 5, 1846), Wells's advertisement[17] indicates resuming "his professional business at his former rooms 180½ Main street. . . ."

Between 1836 and 1846 Wells's office location is given at five different sites, two of which are given two and three different times, respectively, to indicate the opening and closing of his office a total of nine times in that time span.

On April 7, 1845,[18] Wells mentions his ill health and refers his "friends" to Dr. J.M. Riggs in these words: "Dental Notice—Having relinquished my professional business for the present, in consequence of ill health . . . ." It was in January 1845, that Wells's demonstration in

Boston was held "but not with entire success, . . ." ". . . the excitement of this adventure immediately brought on an illness from which I did not recover for many months; . . ." [19] Yet, as noted, the Boston demonstration was late January 1845 and the advertisement did not appear until April 7, 1845.

Sykes,[20] in his "Essays on the First Hundred Years of Anesthesia" asks: "What really possessed Horace Wells that he had such an unhappy and unsuccessful life and such a tragic death? As I see it, he was a man who was easily depressed and discouraged, too easily led and influenced by others; for after one partial public failure, he completely abandoned his attempts to publicize nitrous oxide anesthesia which had already been satisfactory in his hands in a number of cases."

A totally different aspect of Wells's personality, drive, interest, and, in a sense, bizarre behavior, may be drawn from an advertisement in the Hartford Daily Courant of June 2, 1846[20] which reads as follows:

> "Wells' Panorama of Nature"
>
> "H. Wells will give a series of Entertainments, embracing the subject of Natural History, at the *City Hall*, commencing THIS EVENING. Monday June 2d. Major Hamilton's Brass Band will be in attendance. Single tickets 25 cents . . . ."

The events that led to Wells' departure from Hartford (for New York) and his tragic death are also confusing. His newspaper advertisement of February 13, 1847,[22] though date-lined December 19, 1846, announced his association with J.B. Terry. It was shortly thereafter that Wells departed for France (arriving "Boulagne on the sea, Calais, Paris the 26 of February 1847"),[23] strangely, to purchase French paintings for resale in the United States and to present to the French Academy of Science and the French Academy of Medicine his primary role in the discovery of anesthesia. No prior preparation for this presentation was made and for that reason it was not until January 1848 that the Academies acknowledged that role and awarded him the prize of 20,000 francs. Again Sykes notes: "We know that he [Wells] was irresolute, wayward and volatile, for he kept abandoning his dental practice in order to make a living in strange and unusual way . . . ."

Sometime in March 1847 Wells returned from Paris. His next newspaper advertisement, dated July 31, 1847,[24] states "H. Wells will attend to his professional business personally . . . .", implying that J.B. Terry was not, at that time, with Wells; and, finally, on September 4, 1847,[25] Wells notifies his "friends" that he recommends "J.B. Terry . . . in my absence . . . ." And for the first time, in the second portion of that advertisement, nitrous oxide is mentioned and the public assured of its safety and pleasantness.

Wells now departed for New York establishing himself (office and residence) at 120 Chambers Street leaving his wife and son Charles in Hartford to whom "he was so devoted," as drawn by Archer.[3]

Less than five months later, January 23, 1848, Wells committed suicide, at age 33, following his arrest and incarceration resulting from his, admittedly, throwing vitriol on "those frail fair ones who nightly perambulate Broadway . . . ."[26]

The New Haven Journal, dated January 26, 1848,[27] in an article headed "The Suicide of Dr. Wells" speaks of Wells as follows:

> ". . . . It is the belief of medical men here who know all the facts that . . . his whole conduct was the dictate of insanity . . . we were struck with the intellectual merit as well as modesty of the man . . . we formed the opinion that he was subject to great mental depression amounting almost to a disease . . . ."

The article concludes with:

> "He was a man to whom the world owes public thanks for taking the lead in the most wonderful discovery in human history."

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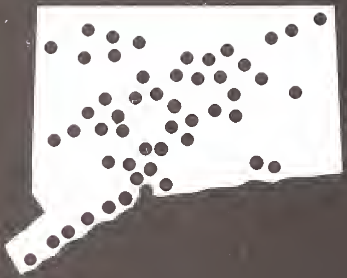

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Introduction

The subject of physician collective bargaining through unionization is one that the Board has encountered before. In Board of Trustees Report F, physician interest in collective bargaining was explored from the perspective of differences between the priorities and interests of organized industrial workers and those of professionals. In that report, the Board concluded that the union movement's traditional emphasis on collective action through strict majority rule is ill-suited to professional values of individualism and autonomy. Organizationally and philosophically moreover, the labor union model comprehends neither of the pursuits that are of paramount importance to physicians organized in professional associations—the advancement of medical science and the promotion of public and patient welfare.

In the years since adoption of Board Report F, legal and socioeconomic developments have made unionization a more attractive, yet less realistic option for the vast majority of physicians. Since 1975, the courts increasingly have subjected practices of the learned professions and their associations to close scrutiny under the federal antitrust laws. As a result, the law has come to circumscribe a progressively broader range of physician conduct. Cognizant of this fact, physicians seek advice with respect to the antitrust impediments to medical society representation of physicians in fee schedule and reimbursement negotiations with business organizations, governmental entities, and private third-party payors. They also seek guidance with regard to methods by which fair representation may be assured in such negotiations.

Legal Risks of Collective Negotiation By Physicians

Antitrust obstacles to joint negotiation of fees and reimbursement levels by groups of physicians or medical societies are formidable. In *Arizona* v. *Maricopa County Medical Society,* the Supreme Court held that it was *per se* illegal for physicians to agree, through participation in foundations for medical care sponsored by local medical societies, on the maximum fees they would claim as payment for services provided to subscribers to FMC-approved insurance plans. These maximum fee levels were determined by use of relative value scales and conversion factor lists formulated and dispersed by the defendants, and were approved by vote of the physician participants in the FMCs.

A *per se* violation consists of conduct that is considered so fundamentally anticompetitive that it may be condemned without regard to its business justifications or proof of specific harm. Significantly, the Court in *Maricopa* was not persuaded that the unusual economic characteristics of the health care market justified an exception to the *per se* analysis applied to price-fixing by purely commercial enterprises. The implications of this ruling are unmistakable—antitrust doctrines developed in the context of pricing behavior of business corporations will be held to apply to professional fee-related conduct with little or no alteration.

It is important to recognize that the law's proscription of "price-fixing" is much broader than its name would suggest. Any combination of competitors having the purpose or effect of raising, depressing, pegging, fixing or stabilizing prices may be condemned as price-fixing. Moreover, a combination of such character may be held unlawful regardless of whether its effect on prices is direct or indirect.

Many kinds of price-related agreements have been declared *per se* illegal as direct price-fixing combinations. An agreement among competitors to fix one element of market price (*e.g.*, a discount level), like an agreement to jointly determine the ultimate price, is *per se* unlawful. Collusive bidding practices also have been held to constitute direct price-fixing. An agreement to adhere to previously announced prices and terms of sale may be condemned *per se* even though the particular prices and terms were not themselves fixed by direct agreement. The courts also have applied the price-fixing rubric to proscribe agreements among competitors to utilize uniform trade-in allowances and standard cash downpayment requirements in automobile purchases, to establish uniform costs and markups, and to specify price differentials between grades of a product.

Agreements among competitors may affect price in an indirect fashion as well. The arrangement may be ambiguous in nature or effect, necessitating analysis of its economic context in order to determine whether it is functionally equivalent to price-fixing. Depending on the facts and circumstances the courts may declare such an agree-

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ment *per se* illegal or unreasonably restrictive of competitive conditions. In *National Society of Professional Engineers* v. *United States,* the Supreme Court invalidated an engineering society's ethical canon prohibiting professional engineers from discussing prices with potential customers until after negotiations had resulted in the initial selection of an engineer. The Court remarked that while this was "not price fixing as such," a full analysis of the market context under the traditional rule of reason was not necessary to demonstrate its anticompetitive nature. It held the canon facially unreasonable because it amounted to a ban on competitive bidding that substantially deprived the customer of the ability to utilize and compare prices in selecting engineering services.

In its most recent decision, the Supreme Court held that the National Collegiate Athletic Association's ("NCAA's") "television plan" for the broadcast of member institutions' football games constituted a "naked restraint" of trade. Under that plan, a committee of the NCAA was formed to exercise exclusive control over television broadcasting of college football games by establishing ground rules under which selected networks could negotiate and contract for telecast rights with NCAA member colleges. The committee controlled the supply of broadcast rights to be made available to networks by limiting the total amount of televised intercollegiate football and the number of games that any one team could televise, and by establishing a uniform price for the broadcast rights of each member that bore no relationship to differences in quality or consumer preference.

The Court characterized the television plan as a horizontal combination of NCAA member institutions that foreclosed competition *inter se* on the basis of price or kinds of television rights that could be offered to broadcasters. It noted that the plan's preclusion of any price negotiation between broadcasters and institutions constituted "horizontal price fixing, perhaps the paradigm of an unreasonable restraint of trade." Moreover, it admonished that a "restraint of this type has often been held to be unreasonable as a matter of law." Most significantly, the Court found that the anticompetitive consequences of the arrangement—individual competitors' loss of freedom to compete, and the negation of consumer preference as a determinant of price and output—were apparent on its face. This reasoning is especially pertinent in evaluating the risks of collective fee negotiation by independently competing physicians.

Several variations on a common theme may be imagined where collective physician negotiations are concerned. Ordinarily, members of an association wish to designate a common negotiation "agent" to bargain on their behalf toward an agreement acceptable to most or all the members. They may appoint a bargaining committee of the association, or form a new entity unrelated to the association to assume this "agency" function. Once finalized, the negotiated purchase contracts probably would be executed bilaterally, although their content essentially would be identical among all similarly situated physicians. Most proposals call for nonexclusive and nonbinding participation by individual physicians; *i.e,* each physician would remain free to reject the collective bargain and negotiate individually for more satisfactory terms. No sanctions or enforcement mechanisms would be provided to compel acceptance of the jointly negotiated contract.

The Supreme Court's *NCAA* decision confirms that the designation of a true common agent with binding authority to conclude an agreement on behalf of independent competing physicians would be considered a *per se* violation of the Sherman Act. An ostensibly nonbinding arrangement enforced by informal methods of coercion very likely would be treated similarly. A nonmandatory, nonexclusive arrangement of the type described above creates less risk of antitrust exposure, but not significantly less.

Under conventional antitrust theories, a combination to fix or tamper with prices may be inferred from circumstantial evidence, including the exchange of certain cost or price data, or information relating to specific transactions. In *United States* v. *Container Corporation of American,* the Supreme Court held that exchanges of information concerning the most recent price charged or quoted by sellers amounted to a *per se* unlawful price-fixing arrangement, even in the absence of an agreement to adhere to a price schedule. The strength of such a conspiratorial inference depends largely on the degree to which economic or other characteristics of the market make it reasonably foreseeable that price stabilization, or a chilling of the vigor of competition, will result from the conduct in question. An inference of collusion may be credited where such anticompetitive effects are foreseeable consequences of the arrangement, notwithstanding the lack of an agreement to abide by the jointly negotiated bargain, or the absence of explicit coercive measures tending toward uniformity of result. Thus under certain circumstances, a finding of tacit conspiracy could result from the pooling of information that normally would accompany even nonbinding, nonexclusive negotiations through a joint bargaining entity.

Furthermore, the Supreme Court's decisions in *Maricopa, Professional Engineers* and *NCAA,* when read together, suggest that a combination to interfere with competitive pricing, even though not explicit price-fixing, will be subjected to liability under the *per se* test or a truncated version of the rule of reason. Under the *Container* rationale, moreover, an inference of collusion may be drawn where circumstances surrounding the arrangement in question make it reasonably foreseeable that price stabilization or uniformity will result from such tampering with the free market pricing mechanism.

In the context of physician joint negotiation proposals, such antitrust vulnerability is established by the expectation on the part of participants that a unified bargaining position will emerge from the process, by the tendancy of group fee "recommendations" to be viewed as collective "demands," and by subtle influences on individual physicians to accept the contract terms ultimately offered. The latter type of informal "enforcement mechanism" could arise from the bargaining entity's practice of advising physician members as to the acceptability or relative worth of offered terms. Payor unwillingness to enter into negotiations with physicians who decline to accept the jointly bargained contract terms also would provide an impetus toward uniformity. Either alone or in combination, these factors create a serious risk that even a nonexclusive, nonbinding collective negotiation arrangement would be viewed as a fee-stabilizing combination implemented by tacit agreement of the participating physicians.

Physicians are well aware that these antitrust impediments to joint negotiation place them at a severe disadvantage in dealing with third-party payors. The Supreme Court has expressly reserved judgment on the question of whether an insurer lawfully may fix a fee schedule for services and enter into bilateral contracts with individual physicians. The lower courts have not considered the practice of limiting reimbursement in accordance with insurer determined maximum fee schedules to constitute horizontal or vertical price-fixing—at least in the absence of evidence demonstrating provider control of the insurer's reimbursement policies.

From the foregoing it is readily apparent that the antitrust risk that inheres in collective activity by independent providers plays a major role in perpetuating the lack of parity in the bargaining process between physicians and third-party payors or purchasers. Cognizant of this fact, physicians have questioned whether the ever-increasing degree of control over their activities exercised by powerful purchasers and third-party organizations would justify a blanket exemption from antitrust strictures such as that applicable to collective bargaining functions of labor unions. The following section examines this and related questions.

Physician Bargaining Organizations Under the Labor-Antitrust Exemption

A. Source and Scope of Organized Labor's Exemption From the Antitrust Laws

Congress has enacted several statutes restricting both the applicability of the Sherman Act to labor and the power of federal courts to enjoin labor activity. Based on those statutes and on the public policies embodied in the federal labor laws, the courts have fashioned two labor exemptions from the antitrust laws—the "statutory" and "nonstatutory" exemptions. These two exemptions attempt to deal with different sets of problems created by conflicts between the competing policies embodied in the antitrust and labor laws. In cases involving antitrust challenges to unilateral labor activities the courts apply the "statutory" exemption; in those that involve challenges to combinations between labor and nonlabor entities they apply the "nonstatutory" labor-antitrust exemption. The statutory exemption is, by far, the more important of the two for present purposes.

In the years immediately following passage of the Sherman Act, courts viewed the collaborative activities of workers as conspiracies, and enjoined strikes as unlawful restraints of trade when a union's conduct or objectives were deemed socially or economically harmful. In the wake of these judicial decisions, Congress enacted several provisions designed to immunize labor unions and labor disputes from challenge under the Sherman Act.

Section 6 of the Clayton Act, 15 U.S.C. §17 (1982), adopted in 1914, declares that human labor "is not a commodity or article of commerce," and *immunizes from antitrust liability "labor organizations" and their members "lawfully carrying out" their "legitimate objectives."* Simultaneously, in Section 20 of the Clayton Act, Congress restricted the powers of the federal courts to issue injunctions against specified employee activities, such as strikes and boycotts, that are undertaken in the employees' self-interests and that occur in the course of disputes "concerning the terms or conditions of employment." U.S.C. §52 (Supp. V 1981).

This protection was reemphasized and expanded in the Norris-LaGuardia Act of 1932 after the Supreme Court, in the *Duplex Printing Press* case, read the Clayton Act to apply only to union activities directed against an employer by its own employees. Section 4 of the Norris-LaGuardia Act specifically prohibited federal court injunctions against single or organized employees engaged in enumerated activities "growing out of a labor dispute." The Act's intended effect with respect to the antitrust laws was stated in Section 5, which declared that no injunction may issue on the ground that "any of the persons participating or interested in a labor dispute constitute or are engaged in an unlawful combination or conspiracy because of the doing in concert of the acts enumerated" in Section 4.

In the National Labor Relations Act of 1935 ("NLRA"), Congress expanded the organizational rights of labor, expressly recognizing employees' rights to organize in unions, to bargain collectively, and to engage in concerted actions. 29 U.S.C. §§157, 158, 163 (1976). Congress also established the National Labor Relations Board ("NLRB") to regulate labor-management relations. The NLRA, and various rules and decisions of the NLRB, contain elaborate provisions whereby an employee group may petition the NLRB for certification as a labor organization entitled to engage in collective bargaining on behalf of an appropriately defined "bargaining unit" of employees. Moreover, the NLRA imposes compulsory collective bargaining with respect to certain matters, and establishes a certified organization as the exclusive negotiating representative for the entire bargaining unit.

In *United States* v. *Hutcheson*, the Supreme Court announced that the Sherman, Clayton, and Norris-LaGuardia Acts must be read as a single "harmonizing text" to define labor's exemption from the antitrust laws. The Court held that labor unions acting in furtherance of their own self interest and not in combination with nonlabor groups enjoy an immunity from Sherman Act liability that derives, not only from the Clayton Act but from the Norris-LaGuardia Act, in which Congress "reasserted the original purpose of the Clayton Act by infusing into it the immunized trade union activities as redefined by the later Act." *Hutcheson* holds, therefore, that federal courts lack authority to issue injunctions applicable to "labor disputes," and that §20 of the Clayton Act "removes all such allowable conduct from the taint of being a 'violation of any law of the United States,' including the Sherman Act." In sum, this statutorily created labor exemption immunizes unilateral union activities from Sherman Act liability to the extent that they are conducted in furtherance of legitimate union objectives and occur in the context of a "labor dispute," as that term is defined in the Clayton Act as read in conjunction with §13 of the Norris-LaGuardia Act (29 U.S.C. §113 *supra*). The *Hutcheson* test remains the governing standard for determining whether labor actions fall within the statutory exemption from the antitrust laws.

The courts have held that a "labor dispute" within the meaning of the Norris-LaGuardia Act must grow out of labor relations, which implies the existence of a bona fide employer-employee relationship. To successfully invoke the statutory labor exemption the antitrust defendant must demonstrate: (1) that the disputing parties stand in the relationship of employer and employee, and that the dispute affects some aspect of that relationship; or (2) that the employer-employee relationship of other parties constitutes the crux of the dispute which precipitated the antitrust claim. Concerted actions relating to controversies upon which an employer-employee relationship has no bearing are entitled to no immunity.

Therefore, when independent businessmen combine, even in the form of a labor organization, they may not invoke the statutory labor exemption to immunize conduct in restraint of trade, since their activities are undertaken to enhance their entrepreneurial interests rather than to affect some employer-employee relationship.

B. The Statutory Labor-Antitrust Exemption As Applied to Physician Organizations

Based on the foregoing analysis, it appears that a union of independently practicing fee-for-service physicians formed for the purpose of collectively negotiating fees and reimbursement or practice conditions with third-party payors, group purchasers of services and hospitals could not avail itself of the statutory exemption. Such a group would not be viewed as a bona fide labor organization, nor would its conduct relate to a "labor dispute" within the meaning of the Clayton and Norris-LaGuardia Acts.

Clearly, since private fee-for-service physicians deal with insurers, purchasers and hospitals as independent contractors, a dispute between their organization and such entities would bear upon no employer-employee relationship between them. Whether the underlying physician-patient relationship provides the requisite nexus with an employment relationship is doubtful.

Examination of the status of physician organizations under the provisions of the National Labor Relations Act offers another perspective on this issue. A "labor organization" entitled to engage in collective bargaining is defined in the NLRA as:

> "[A]ny organization of any kind, or any agency or employee representation committee or plan, in which employees participate and which exists for the purpose, in whole or in part, of dealing with employers concerning grievances, labor disputes, wages, rate of pay, hours of employment, or conditions of work."

The Act also provides that the term "employee" shall not include "any individual having the status of an independent contractor, or any individual employed as a supervisor."

Under the "right of control" test adopted by the NLRB and most courts, the National Labor Relations Board applies the same general agency principles as would the courts in determining whether or not an individual is an employee or an independent contractor. When the party for whom services are performed retains the right to control the manner and means of his performance, particularly when this right extends to the details of the work, the provider of the services is considered an employee rather than an independent contractor. Although this test requires that all of the circumstances surrounding the relationship be evaluated, with no one factor being considered dispositive, the extent of the actual supervision exercised by the putative employer is the most important element to be weighed. Moreover, the control exercised over the manner and means of performance, not merely the economic controls which an employer is able to exercise over those with whom it contracts for provision of services, is the identifying characteristic of an employer-employee relationship.

In applying the control test the NLRB and the courts have identified many factors relevant to the inquiry including: the type of services rendered and the degree of skill necessary to provide them, the right to hire and discharge, the method and determination of compensation, whether the person providing services is engaged in an independent business or enterprise, whether he has an independent entrepreneurial interest in the venture, whether he stands to derive profit from the work of those under him, whether the relationship is of a permanent character, whether tools or materials are furnished and maintained by the employer, and whether the employer has control of the premises where services are performed.

As applied either to the physician-patient relationship or to the relationship between physicians and payors and hospitals, the control test requires that independently practicing fee-for-service physicians be categorized as independent contractors rather than employees. Notwithstanding the fact that payors and hospitals have seized a substantial measure of economic control over the physician's practice, control over the mode and manner of the performance of medical services remains with the physician. Professional autonomy in the arena of medical decisionmaking, moreover, is protected from lay and corporate interference to a great extent by state medical practice acts, or by the public regulatory policies on which they are founded. The NLRB and the federal courts undoubtedly would consider the physician's wide discretion in the exercise of professional skill and judgment particularly persuasive evidence of independent contractor status. When coupled with other relevant factors, as outlined above, the conclusion that independently practicing physicians do not qualify as "employees" under the NLRA becomes all the more compelling.

Professional autonomy in clinical decisionmaking, of course, is not alone determinative. A physician may be treated as an employee for purposes of the labor laws notwithstanding the lack of direct control of the means and manner of his performance of professional services if other indicia of the employment relationship predominate, *e.g.*, payment in the form of a salary, fixed hours of work, use of premises and equipment supplied by the employer, and absence of an assured tenure. The NLRB may certify an organization of such physician employees as a collective bargaining representative of a unit of "professional employees" under the NLRA, 29 U.S.C. §152 (12) (1976).

The term "professional employee" refers to such persons as legal, engineering, scientific, and medical personnel who possess advanced, specialized training and knowledge, are engaged in work that is predominantly intellectual, and consistently exercise judgment and discretion in discharging their responsibilities. The term is not equivalent to "supervisory" employees, who are excluded from the NLRA by its own terms, 29 U.S.C. §§152(3) and (11), 164(a), or "managerial" employees who are excluded pursuant to the legislative policy of the Act. The fact that employees are professionals, however, does not preclude them from also being categorized as supervisory or managerial employees whose organization is ineligible for NLRB certification.

Thus, even persons who are literally "employees" may be excluded from coverage under the NLRA. Similarly, persons who admittedly possess certain employee characteristics may be denied recognition as "employees" for purposes of the Act. The NLRB has consistently adhered to the position that although interns, residents, and clinical fellows possess characteristics of employees, they are primarily engaged in graduate educational training rather than serving the staffing requirements of hospitals. Accordingly, their status is that of students rather than "employees" entitled to the protections of the NLRA.

Although employed physicians may organize themselves for any lawful purpose, their right to do so is of limited value unless it is protected by the provisions of the NLRA. Employers' attempts to discourage their organizational efforts as well as employers' subsequent conduct toward the union are subject to none of the Act's sanctions against unfair labor practices. Thus, an employer is under no duty or legal compulsion to bargain with a physician organization that is outside the scope of the Act's protection. Moreover, retaliatory actions against striking employees may not be actionable under these circumstances.

This is not to say that an organization of employed physicians would be deprived of its statutory exemption from the antitrust laws merely by virtue of its inability to secure NLRB certification. Under the *Hutcheson* test, the exemption derives from provisions of the Norris-LaGuardia Act applicable to persons or associations participating or interested in a "labor dispute" as defined in §13. Thus, an employee organization enjoys immunity to the extent that it acts to advance legimate labor objectives such as wages, hours and conditions of employment, and does not combine with nonlabor groups—regardless of whether it may be certified as an exclusive bargaining agent under the NLRA.

Situations may arise in which an organization of employed physicians attempts to regulate fees or working conditions of certain independent fee-for-services practitioners in order to preserve and protect benefits won from employers through collective bargaining. Ordinarily, a combination between a union and entrepreneurs or independent contractors falls outside the protection of the statutory labor exemption; under limited circumstances, however, independent contractors may be held to constitute a "labor group" entitled to refuge under the exemption.

In *Los Angeles Meat & Provision Drivers Union* v. *United States*, independent contractors combined with a union to enhance their bargaining power in dealing with common employers. The Court held that these independent contractors could be divested of union membership because independent sellers of commodities may not immunize their conduct by calling themselves collectively a union. The Court acknowledged that a labor organization may have a legitimate interest in soliciting self-employed entrepreneurs as members, but added that in the case before it, "there was no job or wage competition or economic interrelationship of any kind" between the entrepreneurs and the other members of the union.

However, the Court has exempted from state antitrust regulation a collective bargaining agreement between the Teamsters union and motor carriers that set minimum rental fees when a carrier leased a truck owned by an entrepreneur driver. Recognizing that the union's objective was to protect its member-drivers' wage scale from being undermined by the lessor-drivers, the Court held that the union could lawfully regulate the terms of employment of the independent contractors because those terms were "of vital concern to the carriers' employed drivers."

In *American Federation of Musicians* v. *Carroll*, the Court exempted direct price restraints imposed upon independent contractor orchestra leaders that operated to protect the wages and other legitimate interests of the employed musicians. There, four band leader members of the federation challenged the union's system of regulating "club dates," or one-time engagements, which included, among other things, prescribed minimum prices, a "closed shop" arrangement, and a stipulated minimum number of instrumentalists. The criterion employed to determine whether the independent contractors were a "labor group" involved in a "labor dispute" under the Norris-LaGuardia Act was whether there was "job or wage competition or some other economic interrelationship affecting legitimate union interests between the union members and the independent contractors." Finding that regulation of "club date" fees was necessary to protect the wage scale and job security of musicians in the bands, the Court concluded that the orchestra leaders' involvement in the union's regulatory scheme created no unlawful combination between "labor" and "nonlabor" groups.

The Supreme Court recently reaffirmed *Carroll* in *H.A. Artists & Associates, Inc.* v. *Actors' Equity Association*, a case in which union regulation of the fees of independent agents was held exempt even though the agents did not compete with actors for wages or jobs. The economic interrelationship between employed actors and agents was such that the agents controlled actors' access to jobs and were in a position to easily evade the union's negotitated wage structure by exacting high commissions from actors they represented in deals with producers. In response to this problem the union established a licensing system for the regulation of agents, prohibiting union members from using an agent who had not met the conditions of licensure – which included, *inter alia*, the agent's agreement not to charge commissions on scale portions of actors' wages, and a further agreement to limit commissions on wages in excess of scale pay. Under these circumstances the Court held that the combination between the union and the independent contractors who agreed to become licensed agents was not a combination between labor and nonlabor groups. Relying on *Carroll*, the Court viewed the agents as a "labor group" engaged in a "labor dispute" as defined in the Norris-LaGuardia Act; hence the licensing restrictions were held statutorily exempt from the antitrust laws.

As the structure of the medical services market continues to evolve, the *Carroll* rationale may assume greater importance. HMOs and other institutions that employ physicians depend for their growth on the continued public perception of these entities as lower-cost alternatives to traditional fee-for-service practice. A physician union that endeavors to enhance the compensation levels and working conditions of practitioners employed by these group health enterprises may find itself undermining employers' competitive viability by narrowing their cost advantage over independent practitioners. Conceivably, the efforts of the union to regulate the fee schedules of independent contractor physicians might be protected under the statutory labor exemption, where necessary to protect the basic wage structure negotiated for its member physicians employed by group health enterprises. These conditions appear sufficiently remote at present to justify little reliance on the *Carroll* rationale, however. Moreover, it is reasonable to expect that if and when the *Carroll* doctrine is applied in the context of physicians fee-setting, its zone of protection will be narrow and strictly construed.

C. The Nonstatutory Labor-Antitrust Exemption As Applied to Physician Organizations

Since the statutory exemption does not apply when a union combines with a "nonlabor group," antitrust immunity is forfeited when a labor organization combines with one or more employers to restrain trade in product markets. Even where union agreements with nonlabor groups effectively shelter the nonlabor groups from competition in product markets, however, public policies underlying the labor laws require some tolerance for the lessening of business competition that ultimately follows organized labor's successful standardization of wages and conditions of employment. National labor policy strongly favors the association of employees to eliminate competition over wages and working conditions. National antitrust policy discourages similar concert of action to eliminate competition in product markets. The Supreme Court has recognized that ". . . a proper accommodation between the congressional policy favoring collective bargaining under the NLRA and the congressional policy favoring free competition in business markets requires that some union-employer agreement be accorded a limited nonstatutory exemption from antitrust sanctions . . . ."

This nonstatutory labor-antitrust exemption has been addressed squarely by the Supreme Court in only four cases since the 1930s, beginning with *Allen Bradley* in 1945 and ending with *Connell Construction* in 1975. The most significant of these is *Local 189, Amalgamated Meat Cutters & Butcher Workmen* v. *Jewel Tea Co.*, in which the Court defined the central issue under the nonstatutory exemption as whether a restriction in a collective bargaining agreement:

> ". . . like wages, and unlike prices, is so intimately related to wages, hours and working conditions that the unions' successful attempt to obtain that provision through bona fide, arm's-length bargaining in pursuit of their own labor union policies, and not at the behest of or in combination with nonlabor groups, falls within the protection of the national labor policy and is therefore exempt from the Sherman Act."

In essence, *Jewel Tea* holds that ". . . a single national policy that harmonizes antitrust and labor policies cannot sensibly provide for antitrust liability for union-employer agreements that are the result of precisely the sort of arm's-length bargaining – especially over mandatory subjects – that federal labor policy authorizes." Not all collective bargaining agreements concerning mandatory subjects of bargaining fall within the nonstatutory exemption, however.

For example, in *United Mine Workers* v. *Pennington,* the Court held that the nonstatutory exemption did not immunize a collectively bargained wage agreement with certain major coal companies that obligated the union to insist on uniform wages with coal companies outside the bargaining unit, where the purpose and effect of the agreement was to drive some smaller companies out of business. The union was held liable as a participant in an employers' conspiracy to eliminate competition even though it sought to standardize wages, hours, and working conditions. The Court emphasized that the agreement committed the union to a negotiating position outside the bargaining unit, in part to confer anticompetitive benefits on the employers. Involvement in the employers' conspiracy was well within the proscriptions of the policies embodied in the antitrust laws, while the union's surrender of its freedom of action with respect to its bargaining policy conflicted with federal labor policy's commitment to the individual, self-contained bargaining unit as the arena for union-employer bargaining.

Also, in *Connell Construction Co.*, the Supreme Court denied nonstatutory exemption to an agreement between a union and a construction contractor that prohibited the contractor's use of any subcontractor with which the union had no collective bargaining agreement. Noting that the restriction was implemented outside of the context of collective bargaining, the Court characterized it as a "direct restraint on the business market" producing substantial anticompetitive effects "that would not follow naturally from the elimination of competition over wages and working conditions." Accordingly, the Court held that the restraint "contravenes antitrust policies to a degree not justified by congressional labor policy, and therefore cannot claim a nonstatutory exemption from the antitrust laws."

These cases indicate that the nonstatutory labor exemption would protect most collective bargaining agreements between employed physician organizations and employers—at least to the extent that the agreements relate to traditional subjects of mandatory bargaining. Efforts to impose restrictions that go beyond proper subjects of bargaining such as wages, hours, and working conditions may expose both the employer and the union to risks of antitrust liability, as would union conduct that has a potential for restraining competion in business markets in ways that would not follow naturally from elimination of competition over wages and working conditions.

In summary, efforts by independently practicing physicians to collectively negotiate fees, reimbursement, or other terms and conditions under which they will provide services under contracts with third-party payors and purchasers expose them to grave risks of antitrust liability. Except for a small portion of the physician population consisting of bona fide employee practitioners, these risks may not be avoided or minimized by seeking to engage in collective bargaining through unions. Physicians entitled to collective bargaining rights as employees enjoy the same protections from antitrust liability afforded other employees and their labor organizations under the statutory and nonstatutory labor-antitrust exemptions.

Alternative Strategies To Promote Fair Representation

Although there are certain activities in which an association or group may not engage without incurring undue antitrust risks, physicians and medical societies may take constructive actions to optimize physician input into some kinds of fee schedule determination, and many programs designed to ensure quality of, and access to medical care. Such actions may include certain initiatives in the private sector, as well as efforts to influence public authorities in a manner favorable to physicians' viewpoints.

A. Private Sector Initiatives

Two primary means exist by which independently practicing physicians may maximize their bargaining strength in negotiations with third-party payors and purchasers while minimizing, to the extent possible, their exposure to risks of antitrust liability. Participation in certain types of Preferred Provider Organizations (PPOs) and Independent Practice Associations (IPAs), although not productive of complete parity of bargaining positions between physicians and payors, enables physicians to avoid serious risks of per se liability and may withstand scrutiny under the rule of reason if appropriately structured.

In PPO arrangements, physicians negotiate fee schedules for medical services and peer review/utilization review standards and procedures that serve to regulate cost and quality of care. "Brokerage" model PPOs—*i.e.*, those structured around an independent intermediary that negotiates bilateral contracts between payors or purchasers and individual providers, integrated group practices, professional corporations and institutions employing salaried staff—afford an optimal combination of enhanced physician bargaining strength and limited antitrust exposure.

IPA arrangements also facilitate physician input with respect to fees and quality assurance measures. By virtue of their integration of service and insurance functions many IPA models have significant procompetitive potentials that may well preclude *per se* condemnation of fee setting by participating physicians. Notwithstanding doubts created by recent judicial decisions, it appears that physician fee determination under closed-panel IPA models in particular, will be upheld as reasonable in light of the substantial business risks underwritten by physicians in many of these arrangements.

To the extent that physicians are willing to forego the advantages of solo and small group practice, another strategy for increasing bargaining power with manageable antitrust risk is to consolidate individual practices into larger group practice partnerships and corporations. Depending on the degree of concentration prevailing in the local medical services market, the merger of existing individual and group practices may proceed unhindered by antitrust intervention until relatively large physician enterprises predominate. As unitary economic enterprises, such merged ventures would be free to establish uniform fees subject only to the strictures of §2 of the Sherman Act, which deals with abuses of monopoly power.

Another private sector initiative available to physicians is participation in local health care coalitions—voluntary groups that attempt to address issues of accessibility, and cost-effective use of high quality health care resources. The provider members of these groups realize that the coalition concept presents a unique opportunity for them to speak to cost control issues, and that failure to exploit this opportunity risks imposition of "solutions" by federal and state governments. The knowledge and expertise that physicians can provide to a coalition will help to ensure that the quality of medical care, including availability and access, is not overshadowed by the concern for reducing the cost of the care. In addition, physician participation in coalitions increases the business community's understanding of medicine's position on health care issues; builds an improved relationship with government, labor, insurance, the public, and the business community; and maintains medicine's leadership role in the health care field.

The escalation of health care costs in recent years is unacceptable to business and government. Therefore, it is inevitable that efforts will be made to control or reduce these rising costs. The business community intends to reduce its own health care costs with or without medicine's participation. By jointly participating in coalitions, however, medicine, business, and other concerned groups can develop solutions which do not diminish the quality or availability of health care.

B. Public Initiatives

One of the most effective and least hazardous methods by which medical societies may represent physician interests regarding fee and reimbursement issues consists of direct efforts to influence the actions and policies of state and federal governments. By lobbying legislatures and by participating in the processes of government agencies and regulatory authorities, medical societies may affect not only the substance of legislation enacted, but the manner of its implementation as well.

These activities are entitled to immunity from the antitrust laws under the *Noerr-Pennington* doctrine. This exception is based on the First Amendment right to petition government and is fairly broad in scope. The protection relates to activities undertaken in good faith to persuade government to take specific actions or adopt certain policies, even if a competitor is disadvantaged by the proposed action and even if the result sought through lobbying is anticompetitive. This immunity will not apply when the petitioning activity is merely a sham to cover a petitioner's efforts to harm competitors directly.

To the extent that petitioning activities result in legislative or regulatory provisions requiring private parties to engage in conduct that exposes them to risks of antitrust liability a distinct but related protection may be available. In enacting the Sherman Act, Congress intended to regulate private action rather than to prohibit a state from imposing restraints on competition as an act of government. To effectuate this legislative intent, the Supreme Court has held that anticompetitive conduct by private parties is shielded from antitrust attack as "state action" if "compelled by direction of the State acting as sovereign." To qualify for this exception from the antitrust laws, a challenged restraint must be clearly articulated and affirmatively expressed as state policy, and the policy must be actively supervised by the State or an agency of statewide authority.

The complementary protections afforded by the *Noerr-Pennington* and "state action" doctrines may be employed to promote legislation requiring physician representation in matters of fee determination, quality assurance and access to care. Notable examples of such legislative provisions include the Workers Compensation Acts of Washington, Texas and New York, and the Maine Medical Assistance Program enabling act.

Pursuant to the Washington Industrial Insurance Act, the Washington Administrative Code provides for a medical advisory and utilization review committee whose members are appointed by the state medical society (except the one osteopathic physician member nominated by the state osteopathic association). The committee functions as an advisor to the state's labor department with regard to policies affecting medical care and rehabilitation, utilization review and the establishment of rules and regulations. In addition, the committee is directed to advise and assist the department in the resolution of disputes between the labor department and medical care providers.

In New York, the Workers' Compensation Law mandates the Chairman of the Workers' Compensation Board to request from the state medical society a report on the fees deemed to be fair compensation for the medical care provided before the Chairman establishes a fee schedule. The 1983 amendment to the Texas Workers Compensation Law provides for the establishment of arbitration panels for the voluntary arbitration of disputed fees and charges in order to assist the Industrial Accident Board in its regulation of medical fees and charges. These arbitration panels are to be composed of representatives from provider groups and from the insurance industry and are to be actively supervised by the Board.

The Maine Medical Assistance Program enabling statute gives the State Department of Human Services the option to establish fee schedules for reimbursement of medical services. However, in establishing the fee schedules, the Department must consult with individual service providers and their representative associations. In addition, the fee schedules must be reviewed annually, and during that annual review, the Department must consult with individual providers participating in the programs and their representative associations and must consider the actual cost of providing specific services, the effect of inflation on the adequacy of the fee schedule, and the obligation under the federal medicaid program to ensure sufficient provider participation in the State's program.

In each of these programs, the statutory language clearly and affirmatively mandates an important role for physicians and their associations, within a framework of State supervision, in carrying out quality assurance functions and formulating fee schedules for services provided. Compliance with these provisions thus incurs little antitrust risk.

Conclusion

The widening disparity of bargaining power between physicians and purchasers of medical services, coupled with increased application of antitrust restrictions to fee and reimbursement related activities of physicians and medical societies, has rekindled interest in securing legally protected collective bargaining rights through unionization. *Except for the relatively small percentage of physicians who practice as nonsupervisory employees, however, organization as a labor union would trigger no exemption from antitrust proscriptions applicable to collective negotiation of fees.* Independently practicing physicians who ally themselves in an organization which they choose to call a "union" thus enjoy no greater freedom than a medical society to engage in collective bargaining. Although physicians may be unable to achieve complete negotiating parity by participating in certain PPO and IPA networks, these forms of partial integration facilitate a closer approximation of provider and payor bargaining positions within acceptable limits of antitrust exposure. Moreover, governmental processes may be employed to promote fair representation of physician interests with a minimum of antitrust risk.

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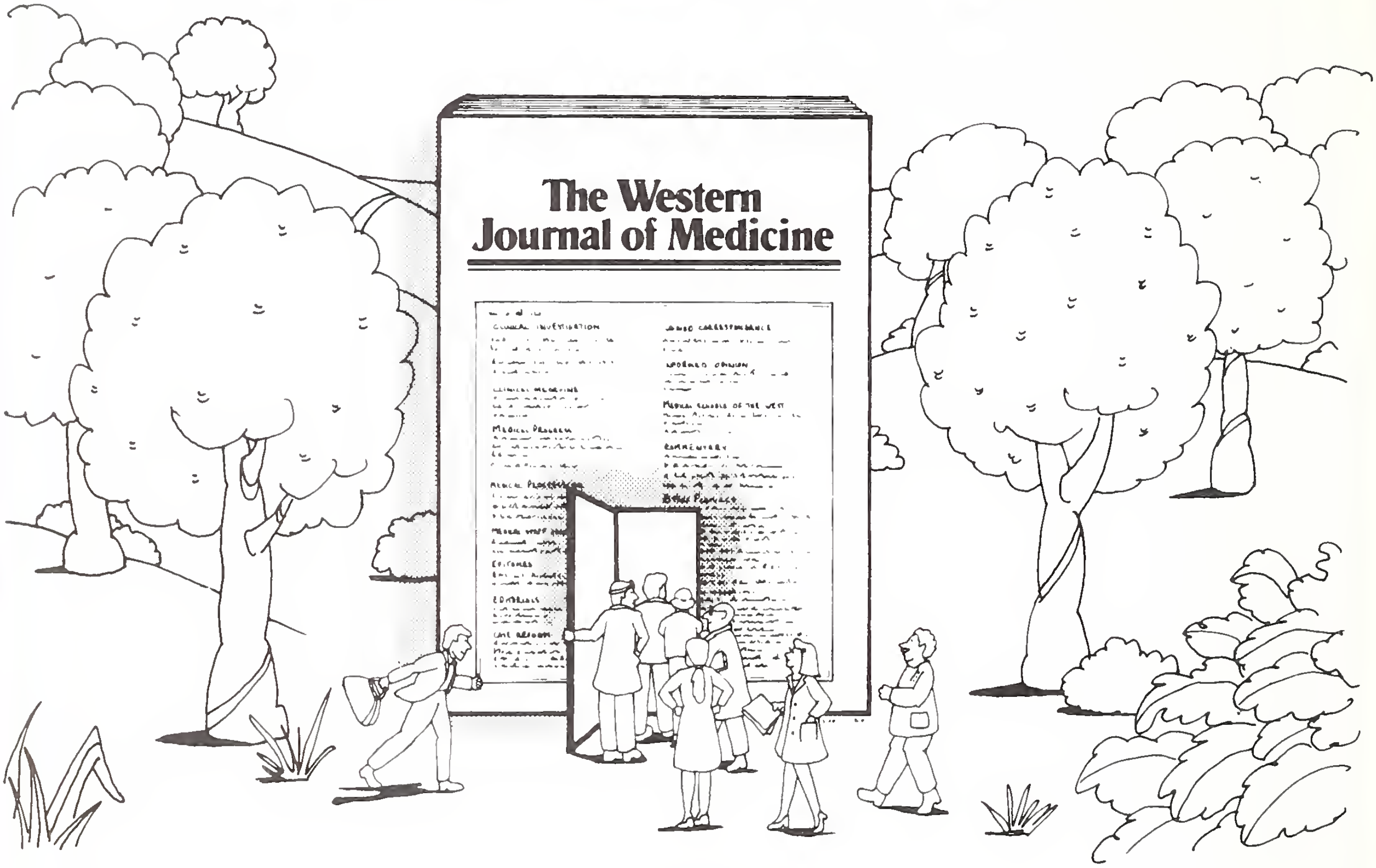
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DRUG INFORMATION UPDATE: HARTFORD HOSPITAL

The Use of Non-Steroidal Anti-Inflammatory Drugs in the Treatment of Pain

DAVID PLATT, PHARM.D. AND PAMELA DOLLERIS, B.S., R.Ph.

Introduction

The non-steroidal anti-inflammatory drugs (NSAID) are a steadily growing class of agents used in the management of pain related problems. (See Table 1) Their value as anti-inflammatory agents and analgesics has been recognized in the treatment of connective tissue diseases and primary dysmenorrhea. However, their value as analgesics in the management of pain due to surgery, trauma, and cancer is probably underrated.

Pharmacology

The precise mechanism of action of the NSAID has not been completely elucidated. The NSAID act peripherally by blocking cyclooxygenase which is responsible for producing the endoperoxide compounds, prostaglandins (PG), thromboxane, and prostacycline, that are involved in the inflammatory process. [1,2] (See Figure 1) These endoperoxides, as well as bradykinin and histamine, are also chemical mediators of pain that are released following tissue damage. PG are unique among these mediators because they can elevate the sensitivity of pain receptors to the chemical and nociceptive stimuli. [3] Another mechanism of NSAID effect involves the elevation of intracellular cyclic AMP which stabilizes lysosomal membranes and prevents release of enzymes involved with inflammation. [1]

The effect of NSAID in some types of cancer pain evolve from the role of PG in bone metastasis. [4] The growth of osseous metastases may be linked to induced bone reabsorption that can be PG mediated. NSAID have been shown to inhibit production of these osteolytic PG, slow the progression of bone metastasis, and elevate the peripheral pain threshold lowered by PG. However, this effect is variable and more data, especially with the newer NSAID, are needed.

The differences between NSAID relative to their pharmcologic effects are unclear. ASA produces irreversible inhibition of cyclooxygenase, whereas the other NSAID are reversible inhibitors. [2] There may also be differences in selectivity of PG inhibition. [4] The clinical significance of such differences is not well understood.

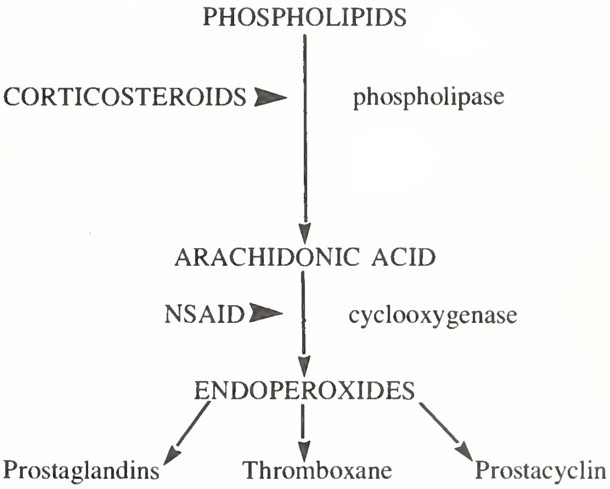

Figure 1
Simplified scheme for prostaglandin biosynthesis

Pharmacokinetics

NSAID are well absorbed from the GI tract. [5] Concomitant administration of food or antacids may slow absorption rate, but has little effect on the extent of absorption. [5] As a class, these agents are highly protein bound which may help to explain their effectiveness in sites of inflammation. [1] Because proteins can diffuse from blood vessels at inflamed sites, NSAID that are bound to them can reach greater concentrations in these inflamed areas. The NSAID exhibit a wide variation in half-life. (See

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Table 1) Therefore, the NSAID with longer half-lives piroxicam and diflunisal, may be administered once or twice daily, respectively.[5]

Clinical Experience

Recently, clinical trials have demonstrated the effectiveness of the newer NSAID in pain management. These studies have evaluated the efficacy of ibuprofen,[6, 7] diflunisal,[8-11] and piroxicam[12, 13] in the treatment of acute pain following trauma, general, gynecological, orthopedic, and oral dental surgery. These trials indicate that NSAID are useful in treating mild to moderate post-trauma or post-operative pain as compared to placebo or other mild analgesics (e.g. ASA, acetaminophen, and codeine combinations). In many cases the NSAID can replace these analgesic combinations. Also, the duration of NSAID analgesia appears to be longer than ASA or acetaminophen plus codeine combinations. The dosage schedules used in these trials are similar to those shown in Table 1. A systematic comparison of 103 studies comparing NSAID was unable to show that one NSAID is more efficacious than another.[14] In patients whose post-operative pain is not expected to be severe, where the threat of respiratory depression, sedation, postural hypotension, or iatrogenic dependence secondary to narcotics is of concern, and who can receive oral medications, the use of a NSAID for pain control is recommended. Patients who fail to respond to one class of NSAID may respond to an agent in another class. Factors such as patient tolerance of side effects and compliance are also important in choosing a NSAID for pain management.

Two recent, randomized double-blind studies in cancer patients with chronic pain demonstrate that the addition of ibuprofen to oral narcotic regimens (including methadone, levorphanol, and oxycodone) can significantly improve analgesia without causing additive sedation.[15, 16] In cancer patients with bony metastases ASA has been shown to inhibit production of osteolytic PG and decrease bone pain.[4] The efficacy of the newer NSAID in bone cancer pain needs further study. In cancer patients, the addition of a NSAID to a pain control regimen may allow for the reduction of narcotic dosage and unwanted side effects. In patients with pain secondary to bone metastases, a trial of a NSAID is recommended.

Adverse Effects

Although generally well tolerated, the adverse effects of NSAID can limit their use in some patients. These untoward effects are mediated through inhibition of PG. For example, PGI has a protective effect on gastric mucosa, and its inhibition by NSAID can predispose patients to ulcerations and bleeding.[17] This effect may be further complicated by the NSAID ability to interfere with platelet aggregation. Recently, attention has been focused on the untoward effects that NSAID can have on renal function.[18, 19] NSAID can cause decreased sodium excretion and fluid retention, followed by pre-renal azotemia, hyperkalemia, oliguria, and anuria. Papillary necrosis, acute interstital nephritis, nephrotic syndrome, and acute tubular necrosis have been reported to occur with NSAID use. The elderly and patients with renal or cardiac disease should be observed closely for nephrotoxicity. Serious

Table 1
NSAID INDICATED FOR THE TREATMENT OF MILD TO MODERATE PAIN.[5]

Class and Generic (Brand) Name	Serum Half-Life (Hrs.)	Suggested Dosage Schedule
Salicylates:		
Acetylsalicylic acid*	2-25	650 mg q 4-6 hrs
Diflunisal (Dolobid)*	8-12	(Load: 1000 mg) 500 mg q 8-12 hrs
Proprionic acids:		
Fenoprofen (Nalfon)*	2.5-3	200 mg q 4-6 hrs
Ibuprofen (Motrin)*	2-4	300-400 mg q 4-6 hrs
Naproxen (Naproxyn)*	10-20	(Load: 500 mg) 250 q 6-8 hrs
Naproxen sodium (Anaprox)	10-20	(Load: 550 mg) 275 q 6-8 hrs
Anthranilic acids:		
Mefenamic acid (Ponstel)	2	(Load: 500 mg) 250 mg q 6 hrs
Oxicams:		
Piroxicam (Feldene)* +	50	(Load: 20 mg) 10-20 mg qd

* Available on HH Formulary

+ Does *not* have FDA approved indication treatment of acute pain hepatic and hematologic toxicities have also been reported secondary to NSAID use.[20] It is not possible to determine which NSAID is best tolerated by patients because of a high degree of interpatient variability.

Conclusion

The growing class of NSAID are demonstrating usefulness in the management of acute and chronic pain syndromes. Their use in certain post-operative situations may allow for reduction in dosage or replacement of narcotic analgesics. The addition of a NSAID in some cancer pain control regimens may also allow reduction of narcotic dosage. In bony metastases, NSAID may have a more specific pharmacologic role in providing analgesia. However, their use should be closely monitored for GI, renal, hepatic, and hematologic toxicities.

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AMA Diagnostic and Treatment Guidelines Concerning Child Abuse and Neglect

AMA COUNCIL ON SCIENTIFIC AFFAIRS

ABSTRACT–Child maltreatment is a serious and pervasive problem. Every year, more than a million children in the United States are abused, and between 2,000 and 5,000 die as a result of their injuries. Physicians are in a unique position to detect child abuse and neglect and are mandated by law to report such cases. These guidelines were developed to assist primary care physicians in the identification and management of the various forms of child maltreatment. A brief historical introduction and specific information about vulnerable families and children are presented. The physical and behavioral diagnostic signs of physical abuse, physical neglect sexual abuse, and emotional maltreatment are delineated. Information about specific techniques for interviewing the abused child and family, case management objectives, reporting requirements, and trends in treatment and prevention are also provided.

Every year, more than a million children in the United States are seriously abused by their parents, guardians, or others, and between 2,000 and 5,000 children die as a result of their injuries.[1,2] Physicians are in a unique position to detect the injuries and behavioral problems resulting from child abuse and neglect. They also have the opportunity to participate in the treatment efforts required to repair damage already done, as well as to prevent further abuse and neglect.

Violence against children has been perpetrated throughout recorded history. Societies for the prevention of child abuse and neglect and concern on the part of government and private agencies developed in the 19th century. Although child abuse may have been identified as a social problem in the last century, it took almost 100 years for violence toward children to be considered a major national problem.

In the 1940s, through the use of diagnostic x-ray technology, physicians began to notice patterns of healed fractures in young children that could only have resulted from repeated blows. Although pediatric radiologists were diagnosing child abuse, it was not until C. Henry Kempe and his associates published their classic work, "The Battered Child Syndrome," in the *Journal of the American*

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From the Council on Scientific Affairs, Division of Drugs and Technology, American Medical Association, Chicago.

Adopted at the Interim Meeting, December 1984, by the House of Delegates of the American Medical Association. These guidelines, submitted by the AMA's Council on Scientific Affairs, were prepared under the guidance of its advisory Panel on Child Abuse and Neglect.

This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve.

Medical Association in 1962 that battering and abuse became a focal point of public attention.[3] As a result, model legislation for child abuse reporting was proposed by four groups: the US Children's Bureau, the Children's Division of the American Humane Association, the American Medical Association, and the Council of State Governments. By the end of the 1960s, all 50 states had passed laws requiring the reporting of child abuse and neglect and had initiated efforts to treat abused children and their families. In 1974, the US government established the National Center on Child Abuse and Neglect to provide a mechanism for increasing knowledge about the causes of child abuse and neglect and to identify steps that can be taken to prevent and treat abuse.

Although much research has been conducted, knowledge concerning the dynamics and effective prevention and treatment of child abuse and neglect is not comprehensive. Nevertheless, physicians have traditionally been at the forefront of activity in this important field of child and family health, and many participate as directors of child abuse programs, through service on multidisciplinary teams, or through private practice.

Child maltreatment is serious and life-threatening, a phenomenon that affects not only children but families and society as well. Children who are abused or neglected must be identified for their own protection. PHYSICIANS AND OTHER PROFESSIONALS PROVIDING SERVICES TO CHILDREN ARE REQUIRED BY STATE LAW TO REPORT SUSPECTED INCIDENTS OF CHILD ABUSE AND NEGLECT. AS MANDATED REPORTERS, THEY ARE AFFORDED LEGAL IMMUNITY FOR SUCH REPORTS. MOST JURISDICTIONS MAY IMPOSE A CIVIL OR CRIMINAL PENALTY FOR FAILURE TO REPORT.

Facts About Child Abuse and Neglect

The causes of child abuse and neglect are complex and variable. Although, in some respects, all families may be vulnerable, it is most useful to understand child abuse and neglect as symptoms of a dysfunctional family.[4] It may be impossible to predict accurately which *individuals* are at high risk as victims or perpetrators, but often it is possible to identify *groups* of people who are at greater risk.

Vulnerable Families

Correlations between child maltreatment and family characteristics that have been identified include the following:

- Child abuse and neglect are reported more frequently in low-income families. (This may be due to underreporting of middle- and upper-class abuse cases.)
- Socially isolated families (ie, families with no external support systems) tend to be more abusive.
- Violence toward children is especially common in families where husbands and wives resort to violence on one another.
- Individuals who are exposed to abnormal child-rearing practices and who are maltreated as children appear to be more likely to become abusive parents.
- Parental expectations inconsistent with the child's developmental abilities often are observed in cases of maltreatment.
- Stressors such as alcohol and drug misuse, inadequate housing (eg, overcrowding), and mental illness are associated with maltreatment.

Biologic parents most often are involved in child maltreatment, but foster parents, adoptive parents, grandparents, siblings, other relatives, friends, and a host of other individuals inside and outside of the home who provide care for children also can be involved.[5]

Vulnerable Children

Characteristics that place children at increased risk for abuse and neglect include:

- Premature birth
- Birth of a child to adolescent parents
- Colic, which renders the infants difficult to soothe
- Congenital deficiencies or abnormalities
- Hospitalization of the neonate, who lacks parental contact
- Presence of any condition that interferes with parent-child bonding[1,5,6]

The etiology of child abuse and neglect is an iteractional one. The primary care physician must take into account social, familial, psychological, and physical factors in developing a treatment plan for the abused or neglected child.

Diagnosis

The physician must conduct a complete physical examination, including developmental testing, on any child who may be a victim of abuse. Laboratory studies (eg, roentgenograms, computed tomographic scan, coagulation studies, and blood tests) are useful in delineating the nature and extent of current trauma and in defining the presence of previous trauma.[7]

During the diagnostic process, the physician should:

- Understand and assess the plausibility of historical and medical antecedents of the child's injury
- Determine the dimensions of continued risk to the child
- Obtain the medical history of the child and family members

Signs of Physical Abuse

It is estimated that more than 125,000 cases of physical abuse occur annually in the United States.[2] Physical abuse is defined as the nonaccidental injury of a child, ranging from minor bruises and lacerations to severe neurological trauma and death.[8] Nonaccidental trauma is the most easily identified type of maltreatment and that most commonly seen by physicians. Characteristically, the injuries are more severe than those that could reasonably be attributed to the claimed case.[9, 10]

PHYSICAL SIGNS

Bruises and Welts

- Face, lips, mouth, ears, eyes, neck, or head
- Trunk, back, buttocks, thighs, or extremities
- On multiple body surfaces or soft tissue
- Forming regular patterns, often resembling the shape of the article used to inflict the injury (eg, hand, teeth, belt buckle, or electrical cord)

Burns

- Cigar or cigarette, especially on the soles, palms, back, or buttocks
- Immersion burns (stocking or glovelike on extremities, doughnut-shaped on buttocks or genitals)
- Patterned burns resembling an electrical appliance (eg, iron, burner, or grill)

Fractures

- Skull, ribs, nose, facial structure, or long bones
- Multiple or spiral fractures
- In various stages of healing

Lacerations or *Abrasions*

- Rope burns on wrists, ankles, neck, or torso
- Palate, mouth, gums, lips, eyes, or ears
- External genitalia
- Body surfaces

Abdominal Injuries

- Bruises of the abdominal wall
- Intramural hematoma of duodenum or proximal jejunum
- Intestinal perforation
- Ruptured liver or spleen
- Ruptured blood vessels
- Kidney or bladder injury
- Pancreatic injury

Central Nervous System Injuries

- Subdural hematoma (often reflective of blunt trauma or violent shaking)
- Retinal hemorrhage
- Subarachnoid hemorrhage (often reflective of shaking)

BEHAVIORAL SIGNS

The abused child is likely to have behavioral problems.[11, 12] The following signs may be seen as either provoking or resulting from abuse. The child may:

- Be less compliant than average
- Exhibit signs of negativism
- Seem to be unhappy
- Be angry, isolated, or destructive
- Display abusive behavior toward others
- Have difficulty in developing relationships
- Display either excessive or complete absence of anxiety about separation from parents
- Display inappropriate care-taking behavior toward parents
- Constantly be in search of attention, favors, food, etc
- Evidence a variety of developmental delays (cognitive, language, fine and gross motor)

Signs of Physical Neglect

Physical neglect seems to be more common than physical abuse. Child neglect can be defined as the failure of a parent or other person legally responsible for a child's welfare to provide for the child's basic needs and an adequate level of care.[8] Neglect tends to be chronic in nature and involves inattention to the child's minimal needs for nurturance, food, clothing, shelter, medical care, safety, and education. Although physicians should be sensitive to the socioeconomic and cultural realities of their patients, it is in the best interest of the child and family to report physical neglect whether or not it results from poverty.

PHYSICAL SIGNS

- Malnutrition
- Repeated episodes of pica
- Constant fatigue or listlessness
- Poor hygiene
    - Unwashed
    - Severe diaper rash
- Inadequate clothing for circumstances

BEHAVIORAL SIGNS

- Lack of appropriate adult supervision
- Repeated ingestions of harmful substances
- Poor school attendance
- Exploitation
    - Forced to beg or steal (food or clothing)
    - Excessive child care and housework responsibilities
- "Role reversal," in which the child becomes a parental caretaker
- Drug or alcohol use

SIGNS OF MEDICAL NEGLECT

- Failure to receive adequate medical attention (In some jurisdictions, these incidents are reportable as *medical* neglect.)
    - Lack of appropriate medical care in the presence of chronic illness
    - Absence of necessary immunizations and medications
    - Absence of dental care
    - Absence of necessary prosthetics, including eyeglasses, hearing aids, etc

Signs of Sexual Abuse

Child sexual abuse is the exploitation of a child for the gratification or profit of an adult. Sexual abuse can range from exhibitionism and fondling to intercourse or use of a child in the production of pornographic materials. Sexual abuse also may result in physical injury or be accompanied by other signs of abuse or neglect. Sexual abuse generally is perpetrated by someone known to the child and frequently continues over a prolonged period of time. Often, it does not involve sexual intercourse or physical force.[13, 14] The incidence is estimated at 100,000 to 250,000 cases per year; however, this type of abuse is difficult to detect and confirm.[4, 5]

PHYSICAL SIGNS

Any of the following physical signs may indicate abuse:

- Difficulty in walking or sitting
- Thickening and/or hyperpigmentation of labial skin (especially when it resolves during out-of-home placement)
- Horizontal diameter of vaginal opening that exceeds 4 mm in prepubescent girls[15]
- Torn, stained, or bloody underclothing
- Bruises or bleeding of the genitalia, perineum, or perianal area
- Vaginal discharge and/or pruritus
- Recurrent urinary tract infections
- Gonococcal infection
    - Pharynx
    - Urethra
    - Rectum
    - Vagina
- Syphilis
- Genital herpes
- *Trichomonas*
- Chlamydial infection when present beyond first six months of life (*Chlamydia* may be present at birth and remain viable for up to six months.)
- Lymphogranuloma venereum
- Nonspecific vaginitis
- Candidiasis
- Pregnancy
- Sperm or acid phosphatase on body or clothes; sperm in the urine of a female child
- Lax rectal tone

BEHAVIORAL SIGNS

Children may display a wide range of psychological reactions to sexual abuse.[16, 17] Reactions depend on the age of the child, emotional maturity, nature of the incident, duration of sexual abuse, and the child's relationship to the offender. The child may:

- Confide in a relative, friend, or teacher; the disclosures may be either overt or subtle and indirect
- Become withdrawn and daydream excessively
- Evidence poor peer relationships
- Experience poor self-esteem
- Seem frightened or phobic, especially of adults
- Experience distortion of body image
- Express general feelings of shame or guilt
- Exhibit a sudden deterioration in academic performance
- Show pseudomature personality development
- Attempt suicide
- Exhibit a positive relationship toward the offender
- Display regressive behavior
- Display enuresis and/or encopresis
- Engage in excessive masturbation
- Engage in highly sexualized play
- Become sexually promiscuous
- Have a sexually abused sibling

Signs of Emotional Maltreatment

Emotional maltreatment may include excessive or unreasonable parental demands on children.[8] Constant or persistent teasing, belittling, verbal attacks, and complete rejection may occur. Parents or caretakers who maltreat children emotionally are frequently unable or unwilling to provide the emotional attention and nurturance necessary for normal growth and development. Since emotional abuse is difficult to define and diagnose, a psychiatric consultation can be useful in documenting and investigating suspected cases.[5] The child may exhibit the following signs.

PHYSICAL SIGNS

- Delays in physical development
- Failure to thrive

BEHAVIORAL SIGNS

- Distinct emotional symptoms and/or functional limitations that can be causally linked to parental management
- Deteriorating conduct
- Increased anxiety
- Apathy or depression
- Developmental lags

The Interviewing Process

The physician should investigate suspected abuse or neglect by interviewing the parents and child.[5, 9] In interviewing the family, the first step is to gather historical and medical data relative to the child's injury. If abuse and/or neglect is suspected, the physician must determine what the level of risk is to the child. Next, the child protection service agency must be informed. Establishing a therapeutic alliance with the family, although not always easy, can facilitate the process. Explaining the reporting process and what the parents can expect to happen often is helpful. A nonaccusatory statement such as, "I am required by law to make a report to the child protective service agency whenever I see a child with an injury (a condition) like this one" can be used.

If the child is to be interviewed for investigative or therapeutic purposes, it may be best, depending on the circumstances, to do so without family members present. The interviewer must be sensitive to the child's fears and apprehension concerning discussion of the home situation and to the child's cognitive development.[9, 11] An audio or video recording of this interview may save the child from having to repeat the story, as well as ensure accurate record keeping. When talking with younger children, it is most facilitative for the interviewer to sit at the child's eye level. Questions beginning with "How come . . ." have been found to be more productive than questions beginning with "Why . . . ." Investigative aids, such as anatomically correct dolls, may help the child to communicate with the interviewer.

Local child protection service personnel may be involved in the initial interview if requested. In cases of severe sexual and physical abuse, where parents may disappear with the child, it is advisable to contact the mandated reporting agency before informing the parents of the suspected diagnosis. Above all else, the primary concern is to protect the child.

When interviewing the child

DO

- Attempt to establish an empathic, trusting relationship
- Conduct the interview in private
- Have the child interviewed by the most experienced professional(s) available in cases of severe sexual and physical abuse
- Explain the purpose of the interview to the child in language appropriate to his/her developmental level
- Always ask the child if he/she has any questions and answer them
- Carefully explain to the child the reason and nature of his/her removal from the home if hospitalization is imminent
- Ask the child to explain words or terms that are unclear to the interviewer
- Use the child's own words and terms in discussing the situation whenever feasible
- Acknowledge that the situation must have been a difficult one for the child and that the child was not at fault
- Sit near the child, not across a desk or table
- Sit at the child's eye level

DO NOT

- Suggest answers to the child
- Press the child for answers that he/she is unwilling to give
- Criticize the child's choice of language
- Suggest that the child feel blame or guilt for the situation
- Leave the child unattended or with unknown persons
- Display shock or horror concerning the child or situation

When interviewing the parents

DO

- Tell the parents the reason for the interview
- Advise the parents of the physician's legal obligation to report cases of suspected abuse
- Conduct the interview in private or, when indicated, with appropriate personnel (eg, child protection service personnel)
- Attempt to be objective
- Reassure the parents of your continued support
- Explain further actions that will be required
- Answer questions honestly

DO NOT

- Attempt to prove abuse or neglect
- Display anger, horror, or disapproval of the parents or situation
- Pry into unrelated family matters
- Place blame or make judgments

Management Objectives

The current understanding of child abuse as a symptom of family distress and a problem with complex, variable origins requires that no one person or profession be solely responsible for the management of these cases. A team of professionals, representing a variety of disciplines, may be best equipped to address the problems of child abuse and neglect. A multidisciplinary team usually provides consultative, diagnostic, and evaluation services.[18] Ideally, the team includes a pediatrician, a social worker, a psychiatrist, a psychologist, a nurse, and an attorney. Other medical specialists can contribute significantly to the diagnosis and treatment of these patients and their families.

The multidisciplinary team should be consulted by primary providers to ensure the quality of services. If a multidisciplinary team is not available, it may be necessary for the physician to help organize and work with other professionals in the hospital or community.

Major management objectives for the physician include the following:

- Identify the child who may have been abused and/or neglected.
- Take emergency measures needed to prevent further injury.
- Provide medical evaluation and treatment of injuries or conditions resulting from abuse and/or neglect.
- Provide an accurate and complete medical evaluation consistent with the diagnosis of child abuse and/or neglect. If court evidence becomes necessary, a well-documented medical record can eliminate or reduce the time a physician may be required to spend in judicial proceedings. Documentation should include:

    A brief description of the nature and extent of injuries and the medical condition of the child (If applicable, the location and nature of the injuries should be recorded on a traumagram.)
    A record of all relevant behaviors and statements of the child and parents
    A complete medical and brief social history if possible

Results of all pertinent laboratory and other diagnostic procedures

Color photographs and roentgenograms if applicable

- Remain objective and nonjudgmental toward parents and child.
- Attempt to establish or maintain a therapeutic alliance with the family. Often the physician is the only professional who maintains contact with the family after other care is terminated.
- Attempt to secure medical evaluation of other children present in the household.
- Report all suspected cases of child abuse and/or neglect in accordance with local statutes.
- Where permissible by law, a physician should hold any abused/neglected child when there is risk of further injury. Children at risk can either be hospitalized by the physician or placed in emergency foster care.

Reporting Requirements

Although child abuse and neglect laws vary among jurisdictions, all statutes include (1) quick identification of the child suspected of being abused/neglected; (2) designation of an agency, either social services or law enforcement, to investigate reports; and (3) provision of treatment services.[10] As mandated reporters, physicians are granted immunity from civil and criminal liability if a report is made in good faith. Most jurisdictions impose a criminal or civil penalty for failure to report. Physicians are advised to obtain a copy of their jurisdiction's child abuse and neglect reporting laws from their medical society or local child protection service agency.

WHAT TO REPORT

- Suspected incidents of nonaccidental trauma, sexual abuse, neglect, and emotional cruelty by an adult.
- Instances in which the child is deprived of the right to adequate nurturance, health, education, and safety.

If the physician is in doubt about the appropriateness of a report, informal peer consultation can be useful.

Once a report has been filed, the child protection service agency may conduct an investigation. If the suspected incident of child abuse or neglect is substantiated, several outcomes are possible. Counseling or psychotherapy may be provided, foster placement may be arranged, or criminal charges may be filed, depending on the circumstances. The physician may want to coordinate with the protective services agency by maintaining telephone contact or correspondence in order to provide follow-up care.

Trends in Treatment and Prevention

The physician's role in the treatment of child abuse and neglect historically has been one of detection, medical diagnosis, and treatment or referral. However, the role of the physician can be greatly expanded. Physicians may serve on hospital child protection teams, provide medical services to private service agencies, participate on community multi-disciplinary review boards, and participate on advisory boards of voluntary agencies (eg, Parents Anonymous). Physicians also may work with local child protection agencies to develop a follow-up mechanism for reported cases.

Physicians can participate in the primary prevention of child abuse and neglect as well. Expanded well-baby care, augmented information and education, and referrals to community resources may be provided for "high-risk" parents. Physicians also may participate in changing hospital childbirth procedures to facilitate parent-infant bonding and support early education in child development and care.

Comprehensive prevention strategies should be directed at increasing parents' (or future parents') knowledge of child development and the demands of parenting. Parent-child bonding, emotional ties and family communications, and home and child management issues should be addressed. These same strategies may be used to strengthen parents' skills in coping with the stresses of infant and child care and, in particular, caring for children with special needs. Approaches to prevention should attempt to reduce the burden of child care, family isolation, and long-term consequences of poor parenting. Increased access to health and social services for all family members is another goal of any prevention effort.

Physicians can actively participate in national, state, or community programs that are directed at achieving these goals. In addition, they can urge their spouses to organize and become involved in auxiliary child abuse prevention programs.

Appendices presenting state-by-state child abuse laws and mandated reporters, a sample "traumagram" (graphic representation of the body for purposes of documenting injuries), and addresses of state reporting agencies are available through the Department of Human Behavior, American Medical Association.

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Update: Acquired Immunodeficiency Syndrome—United States

CENTERS FOR DISEASE CONTROL

Between June 1, 1981, and January 13, 1986, physicians and health departments in the United States notified CDC of 16,458 patients (16,227 adults and 231 children) meeting the acquired immunodeficiency syndrome (AIDS) case definition for national reporting.[1-3] Of these, 8,361 (51% of the adults and 59% of the children) are reported to have died, including 71% of patients diagnosed before July 1984. The number of cases reported each 6-month period continues to increase, although not exponentially, as evidenced by the lengthening case-doubling times (Table 1). Cases have been reported from all 50 states, the District of Columbia, and three U.S. territories.

Adult Patients

Among adult AIDS patients, 60% were white; 25% black; and 14%, Hispanic. Ninety percent were 20-49 years old, and 93% were men. Although the race, age, and sex distribution of adult AIDS patients has remained relatively constant over time, significant changes have occurred in the distribution of specific diseases reported. *Pneumocystis carinii* pneumonia (PCP) continues to be the most common opportunistic infection reported among AIDS patients, accounting for 43% of reported opportunistic diseases; incidence of PCP continues to increase relative to other reported opportunistic diseases among AIDS patients ($p < 0.0001$). PCP accounted for 35% of the diagnosed AIDS-associated diseases before January 1984 and 47% of those diagnosed from January 1985 to December 1985. The increase in PCP was associated with a decrease in Kaposi's sarcoma (KS), the second most common AIDS-associated opportunistic disease. Before December 1984, KS accounted for 21% of reported diagnoses; between January 1985 and December 1985, KS accounted for 13% of reported diagnoses. Among all AIDS patients, 63% have been diagnosed with PCP; 24%, with KS; 14%, with candida esophagitis; 7%, with cytomegalovirus (CMV) infections; 7%, with cryptococcosis; 4%, with chronic herpes simplex; 4%, with cryptosporidiosis; 63%, with toxoplasmosis; and 3%, with other opportunistic diseases only. These values tend to underestimate the number of diseases diagnosed in a given patient, because health-care providers frequently do not provide follow-up information on diseases that occur after the case has initially been reported.

Table 1
Acquired immunodeficiency syndrome cases, by date of report and doubling time—United States, through January 13, 1986

Cumulative cases reported	Date		Doubling Time (months)
129	September	1981	–
257	February	1982	5
514	July	1982	5
1,029	January	1983	6
2,057	August	1983	7
4,115	April	1984	8
8,229	February	1985	10
16,458	January	1986	11

—*Morbidity and Mortality Weekly Report*, January 17, 1986/Vol. 35, No. 2.

A total of 15,243 (94%) AIDS patients can be placed in groups[*] that suggest a possible means of disease acquisition: men with homosexual or bisexual orientation who have histories of using intravenous (IV) drugs (8% of cases); homosexual or bisexual men who are not known IV drug users (65%); heterosexual IV drug users (17%); persons with hemophilia (1%); heterosexual sex partners of persons with AIDS or at risk for AIDS (1%); and recipients of transfused blood or blood components (2%). The remaining 984 (6%) have not been classified by recognized risk factors for AIDS.

AIDS patients reported as not belonging to recognized risk groups are investigated by local health officials to determine if possible risk factors exist. Since 1981, 1,206 AIDS patients reported to CDC were initially identified on the original case report form as not belonging to a risk group. Of these individuals, 398 were from countries where heterosexual transmission may account for many AIDS cases. Of the remaining 808, information was incomplete on 178 patients due to: death (116), refusal to be interviewed (24), or loss to follow-up (38). Two hundred ninety-seven cases are still under investigation. Interviews or other follow-up information were available on the remaining 333 patients. Based on this information, risk factors were ultimately identified in 197 (59%) individuals; 25 (8%) were found not to meet the criteria of the surveillance definition for AIDS and no risk was identified on 111 (33%) AIDS patients. In interviews of the 111 patients for whom no risk was identified, 39 (35%) gave histories of gonorrhea and/or syphilis, indicating that these AIDS patients were at risk for other sexually transmitted infections. Of 57 men interviewed, 15 (26%) gave histories of sexual contact with a female prostitute.

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[*] Patient groups are hierarchically ordered; patients with multiple risk factors are tabulated only in the group listed first.

Reported cases have increased in all patient groups. The relative proportion of AIDS cases among most risk groups has remained stable. The proportion of AIDS cases associated with blood transfusions has increased from 1% to 2% ($p < 0.015$). Due to the long period between infection with human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV) and development of AIDS, the impact of serologic screening of blood donations and deferral of those at increased risk cannot be expected to be reflected yet in national AIDS reporting. In the groups not classified by recognized risk factors, the proportion of AIDS patients born outside the United States has declined from 4% to 2% ($p < 0.0001$).

Pediatric Patients

Among 231 AIDS patients under 13 years old, 19% were white; 60%, black; and 20%, hispanic. Fifty-five percent were male. Fifty-eight percent were diagnosed with PCP; 19%, with disseminated CMV; 15%, with candida esophagitis; 6%, with cryptosporidiosis; 4%, with KS; and 22%, with other opportunistic diseases only. One hundred seventy-four (75%) pediatric patients came from families in which one or both parents had AIDS or were at increased risk for developing AIDS; 33 (14%) had received transfusions of blood or blood components before onset of illness, and 11 (5%) had hemophilia. Risk-factor information on the parents of the 13 (6%) remaining cases is incomplete. Although 57% of pediatric patients have been reported within the last year, 72% were actually diagnosed before 1985. Pediatric patients have been reported from 23 states, Washington, D.C., and Puerto Rico; cases reported per state ranged from one to 91 (median three). Seventy-five percent of the cases have been reported from New York, Florida, New Jersey, and California.

Editorial Note

The incidence of AIDS continues to increase. In 1982, 747 cases were reported; in 1983, 2,124 were reported (a 184% increase); in 1984, 4,569 were reported (a 115% increase); and in 1985, 8,406 were reported (an 84% increase). From analyses of past trends, further increases are expected for 1986; however, the percentage increase in 1986 is likely to be smaller than that noted in 1985.

The number of AIDS cases that have not been classified into previously identified risk groups is not increasing proportionately faster than the number of cases in identified risk groups. Past experience would suggest that many cases currently under investigation will be reclassified.

Currently reported AIDS cases have resulted from HTLV-III/LAV exposure up to 7 years before diagnosis;[4] the possibility of longer incubation periods cannot be excluded. Since HTLV-III/LAV infection persists in an individual, persons previously infected continue to remain at risk for developing AIDS. Due to the long period between infection and development of AIDS, transfusion-associated cases are expected to continue.[4] However, voluntary donor deferral by those at increased risk for AIDS and serologic testing of donated blood and plasma for HTLV-III/LAV antibody—implemented in March 1983 and spring 1985, respectively—have greatly reduced the potential for HTLV-III/LAV transmission through transfusion.[4-6]

The increase in previously diagnosed pediatric AIDS cases reported within the past year reflects improved reporting as well as inclusion in the case definition of histologically confirmed diagnoses of chronic lymphoid interstitial pneumonitis in children under 13 years of age.[3] Since most pediatric AIDS cases result from perinatal transmission of HTLV-III/LAV, the race/ethnicity and geographic distribution of pediatric AIDS patients is similar to that of reported AIDS cases among adult females.

Planned prospective studies of incidence and prevalence of HTLV-III/LAV infection should determine whether current reports of patients meeting the AIDS case definition for national reporting accurately reflect the distribtution of infected persons. Persons meeting the AIDS case definition are only a small percentage of all persons infected with HTLV-III/LAV.[7] CDC uses the existing case definition for surveillance purposes, because other manifestations of HTLV-III/LAV infection are less specific and less likely to be consistently reported nationally.

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The President's Page

Rationing and Free Choice

Apparent costs savings have been recently achieved following the institution of bureaucratic regulatory controls. Realistically speaking, the aura of success will be a transient sensation. The major underlying causes of future cost increases are still in place, namely, inflationary trends, increasing labor costs, changing demographics, and progressive technical advances. Present day cost containment measures including DRG's, PRO activities, the advent of PPO's and HMO's will ultimately not solve the cost problem. Costs will continue to rise amidst the consternation and reactions of business, government and the public. Cost control measures will have soon had maximal effect. At that point, services will have to be denied. Medical care is already being rationed. Some believe that rationing is inevitable under any system.

Is full scale rationing of medical care a realistic future possibility in America? At the present time, it is unlikely that Americans would accept the concept of rationing as willingly as the British. Our economy is better than that of Great Britain. The average British citizen accepts scarcity of resources and is conditioned not to ask for more than is available. They believe that allocation of treatment should be based on the availability of resources. Presently, the British have a strong affection for the National Health Service perhaps second only to the Queen.

Today, America is involved in a generational metamorphosis which involves the emergence of "the Baby Boomers and Yuppie" generation. This is a group of individuals which is very optimistic projecting a feeling of a great sense of destiny. They will become intricately involved in governmental decisions. It is a generation which is perhaps more materialistic and will be asking for freedom without restriction. It is a generation which is very concerned over its health status. They may not readily accept scarcity and allocation of medical care based on resources.

With the proliferation of Alternate Health Care Delivery Systems, the "gatekeeper" concept is being established as a guardian of financial expenditures. The "gatekeeper" concept is a necessary basic component to any rationing program and is the precursor of a potential full scale rationing system. Definitive ongoing care will be denied at the "gatekeeper" level. Physicians, not the bureaucracy, will act as Society's triage agent in the rationing process. Gatekeepers will have to find ways to reconcile the economic limitations of their own professional values. They will be forced to accept standards that influence medical judgments in favor of economic considerations. The "gatekeeper" must be carefully monitored and controlled.

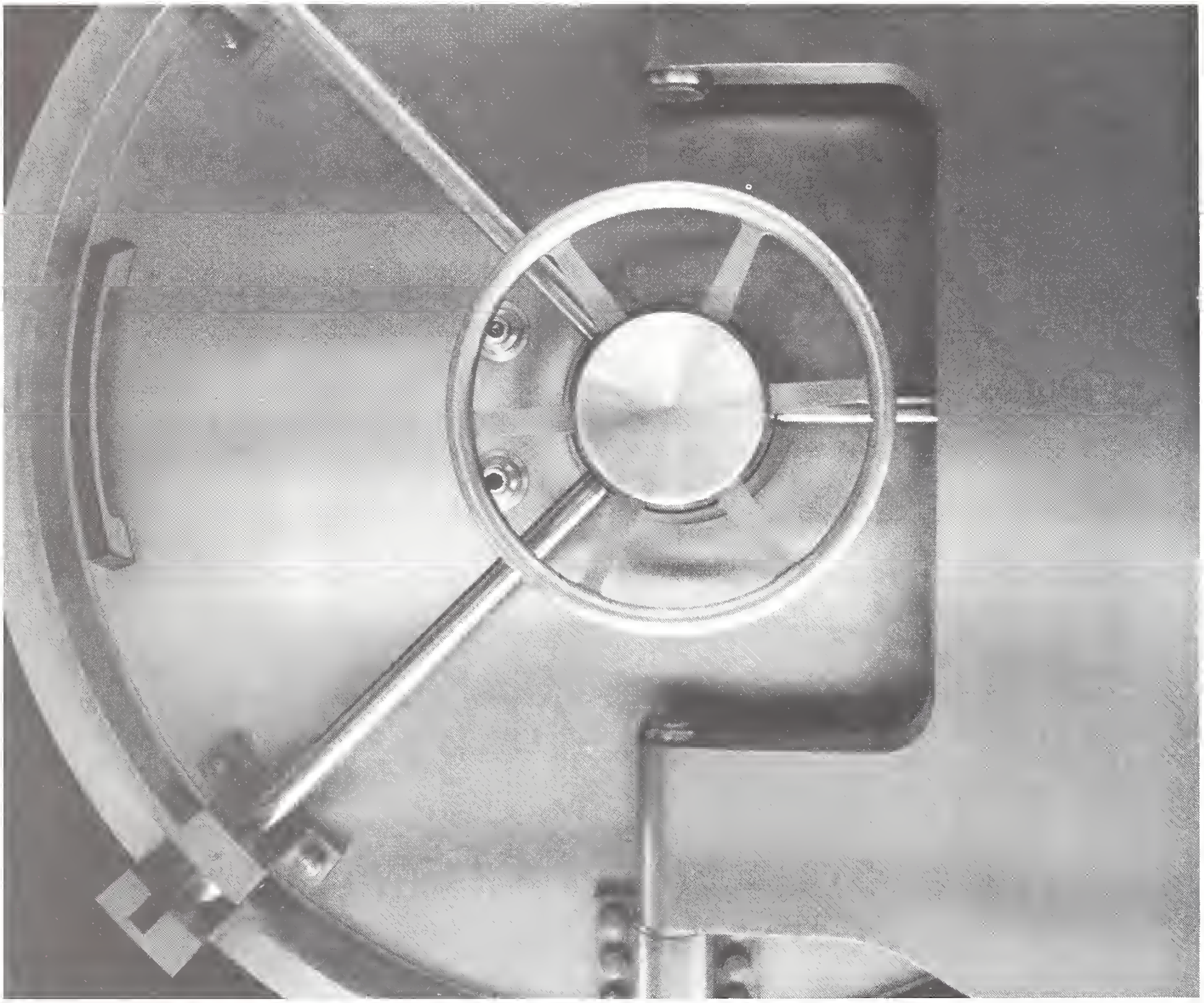
With the passage of the Deficit Reduction Act, further reimbursement cuts in the Medicare system are scheduled to occur. The elderly will be forced to accept the rationing of medical care or to pay individually for their services. The Medicare population is one which has hopefully looked forward to fulfilling its life expectancy but more importantly to maintaining a survival free of disabling, painful handicaps. Rationing of medical services will inevitably be less concerned over the preservation and protection of the quality of life of the elderly.

My appeal at this time is that whatever degree of rationing is employed in the coming years that we as physicians respond to the global needs of our patients and do not reflexly as "the gatekeeper" prevent the patient from exerting his or her right of "free choice" of therapy because of predetermined standards of Third and "Fourth Party" payors based on cost factors alone.

For example, at present, reimbursement for the implantation of permanent pacemakers in Medicare recipients with specific cardiac conditions such as in some patients with myocardial infarction and left bundle branch block or sick sinus syndrome is denied because the mortality without implantation amounts to only 1-2%. The government has a right to determine what it will and will not support financially, but we as physicians should not allow these economic considerations to prevent us from informing this subset of patients of the potential mortality if the pacemaker is not implanted. In other words we should obtain Informed Consent *not to implant or treat* as well as *to implant or treat.* Provided the facts, we should allow the patient to make the final decision.

As the rationing movement proceeds in a rational or irrational manner, remember the words of the New York Times Editorialist, Harry Schwartz, "the ultimate economy in medical care is death." Let us be mindful of the total needs of the living patient and not to deny him "free choice" of medical care based on statistics influenced strictly by cost measures alone.

William A. Whalen, M.D.
President



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Reflections on Medicine

Right Thing, Wrong Reason

ROBERT U. MASSEY, M.D.

"Researching one's customers is not entirely new to hospitals," I read recently in an article on hospital marketing, which went on to recommend that we study who, what, when, why and how the "market buys."

Unless I am attaching private and unsupportable meanings to words like *buy, market, product,* and *customers,* the ideas which these words evoke for me have little to do with the profession of medicine or the provision of hospital services, as I have understood them.

Let me be clear. We all know that market forces work in a statistical way to generate demand, encourage supply, and determine the price of all goods and services, whether these be psychoanalysis, heart transplants, paper clips, or child pornography. The businessman studies these market forces to find ways to increase his share, to maximize his profit, to stay in business. This is his proper goal, the strong motivating force of self-interest which drives him and drives the economy; he may be altruistic along the way—out of beneficence, or to enhance his profit, or both—but altruism is not, except in the most unusual instance, his reason for being in business.

In medicine, on the other hand, profit is not the goal; its purposes are moral; if not, something fearful and perverted comes into the work, dangerous for both practitioner and patient. In Utopia all work is said to be moral, done for the love of mankind and for the sake of the craft, but we know we have here no utopia, and enlightened self-interest is the best guide we have in our present stage of moral development for doing most of the work of the world. In medicine, in education, in art, in science, in religion, however, it is otherwise; in these vocations service, craftsmanship, and discovering the good, the true, and the beautiful are the ends and the rewards. The product of the hospital and the work of the physician, while they clearly have their markets, should never be shrewdly planned with the aim to bring in the greatest profits.

Consider for a moment the first-rate works of art, literature, science, and medical research; these were not products designed for a market to assure a return on invested capital, although they generally flourished in those times and places where business was good and the economy strong. The great medical institutions would never have been built had profit been the motive, though they were built in large part by the means and through the efforts of those who had made their profits in other enterprises. Medicine, as well as science and art, has been symbiotic with a free market economy, the one thriving wherever the other flourishes, and each operating honestly in accordance with its own principles.

Many years ago when I was a senior resident, my chief, in a conversation after rounds, remarked that our hospital, like all great hospitals, was a public trust, and that as physicians we had an unconditional obligation to serve. There was no other reason, he said, for us to be around. It seemed to me that he was only saying what we both had known in our bones to be true. Suppose he had followed this by alluding to product configuration, pricing options, and advertising to attract new customers; I would have taken it all for a joke, an exercise in irony.

I showed the marketing article to a second-year medical student; he saw no joke, said his classmates worried about the commercialization of medicine, feared becoming lackies for bureaucrats or corporate bosses, and hoped that "this madness would pass by the time they entered practice." "Styles change," I said, "but for now there are too many doctors, too many hospital beds."

The comradeship between medical institutions and the corporate model is new-hatched; investor-owned hospitals have been around for years, mostly as small second-rate operations, but now their profitability, respectability, and growth are new and threatening; mergers, chains, and multi-dimensional integrations are all the rage; the clinical work of the hospital seems to have taken second place to corporate restructuring to meet the challenge.

Until now, the quality of care and dedication to the principles of medicine have probably suffered very little; those who are running the new schemes grew up in the old institutions, learned all the right values. Most of them, we may suppose, will hold fast to their principles. But what about those who follow (the young are malleable, the marketers say), what about the inexorable wearing effect, like waves upon rock, of the demand for profits and the urge to create monopolies, to capture more of the market, to stimulate demand where none existed before? What about the price that investors must require to stay in the market? What finally must be the effect of price competition upon the beneficent principles of medicine?

ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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Artificial Feeding: Controlling the "Technological Imperative"

JOSEPH M. HEALEY, J.D.

A central feature of the California Court's examination of the withdrawal of artificial feeding in the *Barber* case[1] was the court's conclusion that since artificial nutrition and hydration were more similar to other medical procedures than to usual means of providing nutrition and hydration, their use need not be viewed as legally required in every case. Rather, as is the case with other medical procedures, an evaluation of the benefits sought and the burdens imposed should be made to determine whether their use actually contributes to the patient's well being. This conclusion acknowledges that medical procedures of any sort do not automatically provide net benefit to the patient and that there are circumstances in which the use of such procedures is neither legally nor ethically required. Such an analysis challenges the "technological imperative" which mandates that whatever interventions are available should be used under all circumstances. It is this effort to control medical technology and to channel its use as a vehicle of service rather than enslavement which is influencing the development of public policy in this area and which provides an appropriate focus for this concluding column in the three part series on artificial feeding.

Doctors have legal and ethical obligations to use their clinical skills to enhance the well-being of their patients. These obligations arise out of such fundamental ethical concepts as beneficence and non-maleficence and out of the contractual and quality assurance dimensions of the doctor-patient relationship. Stated succinctly, doctors are expected to use their clinical judgments in an assessment of the patient's condition, in their recommendations of appropriate care and treatment, and in their management of the patient's care. It has long been recognized that one limit on the doctor's duty to provide treatment involves the absence of any obligation to use non-efficacious treatment. The Barber case[2] cites with approval an article discussing this principle as applied to respirators:

> "A physician is authorized under the standards of medical practice to discontinue a form of therapy which in his medical judgment is useless...If the treating physicians have determined that continued use of a respirator is useless, then they may decide to discontinue it without fear of civil or criminal liability. By useless is meant that the continued use of the therapy cannot and does not improve the prognosis for recovery."[3]

If one accepts the court's conclusion that artificial feeding ought to be treated in the same manner as other medical procedures, then the key question becomes the determination of the usefulness of the intervention in light of the patient's condition and of the burdens imposed by the intervention itself. This would require a careful evaluation of the patient's condition, of the role of artificial feeding in the care and management of the patient and of the balance between the benefits anticipated and the burdens imposed. At issue is the traditional distinction between "ordinary" care and "extraordinary" care. As the President's Commission pointed out:

> "If the ordinary/extraordinary distinction is understood in terms of the usefulness and burdensomeness of a particular therapy, however, the distinction does have moral significance. When a treatment is deemed extraordinary because it is too burdensome for a particular patient, the individual (or a surrogate) may appropriately decide not to undertake it. The reasonableness of this is evident—a patient should not have to undergo life-prolonging treatment without consideration of the burdens that the treatment would impose. Of course, whether a treatment is warranted depends on its usefulness or benefits as well. Whether serious burdens of treatment (for example, the side effects of chemotherapy treatments for cancer) are worth enduring obviously depends on the expected benefits—how long the treatment will extend life, and under what conditions. Usefulness might be understood as mere extension of life, no matter what the conditions of that life. But so long as mere biological existence is not considered the only value, patients may want to take the nature of that additional life into account as well.
>
> This line of reasoning suggests that extraordinary treatment is that which, in the patient's view, entails

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significantly greater burdens than benefits and is therefore undesirable and not obligatory, while ordinary treatment is that which, in the patient's view, produces greater benefits than burdens and is therefore reasonably desirable and undertaken."[4]

Connecticut does not yet have case law directly dealing with the withholding or withdrawal of artificial feeding. The framework suggested in the California decisions makes very good sense. It is time to recognize that our technological innovations must not be used simply because they exist or as a means to prolong the dying process. Rather, they must be used as instruments of compassionate care to enhance the patient's well-being. Assuring such use is not an easy matter. However, the increased acceptance of the framework suggested by the California court would go a long way toward encouraging responsible decision-making by physicians, patients and family members.

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Editorial

The Liability Insurance Crisis

(The following letter from CSMS was written in response to a recent New Haven Register *Op-Ed article which questioned the existence of a crisis in medical malpractice litigation.)*

Mr. Lee Grabar
Chief Editorial Writer
Jackson Newspapers
40 Sargent Drive
New Haven, CT 06511

Dear Mr. Grabar:

With respect to Dr. John Maher's article entitled "Malpractice Suits Produce a Political Crisis," there is far more to the issue than he suggested. It is hard to believe that his discussion of the subject did not include a single word about the very reinsurance facet of the overall crisis. In addition to this major omission, the article also carried several inaccuracies.

Dr. Maher may not be aware of the massive reinsurance crisis which has touched almost every person in the country. Reinsurance, which insures insurance companies against catastrophic losses, has become difficult to secure even at inflated prices. Every town and municipality in Connecticut and throughout the United States has encountered huge premium increases for liability insurance and a number of them have had their coverage cancelled entirely. Why the problem? According to insurance analysts, the primary reason for escalating premiums lies with the courts, which are handing out increasingly large settlements in cases against municipalities. Experts say that people sue municipalities because they believe towns and cities have deep pockets.

Lloyd's of London, one of the world's biggest and perhaps best known reinsurers, shocked the insurance industry earlier last year when it announced that it lost money for the first time in its 300 year history. It blamed liability litigation in the United States for the crisis market and claims that a great majority of its losses comes from this country, which generates only a small portion of its overall business. Because of these exorbitant losses. Lloyds has threatened to withdraw from the U.S. market.

Liability insurers lost some $21 billion during 1984 and the dangerous trends are there to indicate that losses could be worse in 1985. These are some of the reasons why municipalities and businesses are having such difficulty securing liability coverage, even at excessive rates. This litigation madness has also caused massive premium increases for physicians and manufacturers, hotels and motels, restaurants, bars, contractors, architectural and accounting firms, taxi and limousine operators, ice skating rinks and literally all other individuals and business which must have liability protection.

Connecticut physicians' premiums have doubled in the past three years and quadrupled in the past six. In an attempt to stabilize premiums and guarantee the availability of professional liability or malpractice insurance for Connecticut physicians, the Connecticut State Medical Society established the Connecticut Medical Insurance Company which began operations on October 1, 1984. A brand new insurance company like CMIC would not expect to be faced with many claims during its first few years, and yet on its first anniversary, it was forced to raise its premiums by 17.6% for the first million dollars of coverage—a hike criticized by some as not being enough. On losses exceeding $1 million, reinsurance for its second year cost 212% of the first year's figures!

Dr. Maher suggested that "weeding out the few incompetent physicians responsible for most malpractice suits would help solve the malpractice insurance crisis." Were it only that simple! It is well-known that most suits are filed against the best-trained, highly-skilled physicians at the peak of their careers. The rate of claims has doubled in the past six years; despite the fact that we have the finest medical care system ever devised with the best-trained physicians the latest and best technology. The record speaks for itself. The development of ultrasound, more sophisticated treatment for burn patients, transplants and bypass surgery, magnetic resonance imaging and

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many other new technological advancements in medicine have enabled people to live constructive and productive lives who once were considered hopelessly doomed. More than one-half of all the diagnostic and therapeutic tools used by doctors today did not exist anywhere in the world just ten years ago.

The present liability insurance crisis, which has affected every sector of our society, also threatens availability of health care for the public. Premiums in New York and Florida have surpassed $100,000 for some physicians, and many doctors have taken early retirement or reduced the range of their practices. For example, 10% of *all* obstetricians have quit the practice, another 10% are cutting back in the scope of their practices, and still another 18% have refused high risk and difficult cases. And yet, there are no areas of medicine where greater advances have been made over the past few years than in perinatal, neonatal, and postnatal care. Thousands and thousands of infant lives have been saved that heretofore would not have had a chance for survival. It is ironic that this is the very area in which suits are increasing at the fastest rate. When a physician is dealing with such a high-risk group of patients, there are inevitable mishaps and untoward results that may not involve any negligence but still end up in the courts. Unless the alarming trends are arrested, Connecticut physicians will soon pay New York style premiums which could impact on health care availability as they already have on rising health care costs. Connecticut businesses have the same problem with product liability, and Connecticut residents will either encounter higher taxes or reduced services in their municipalities if the crisis is not addressed.

One of the real tragedies of this crisis, and which attests to the inequities of our present tort system, is the plain and simple fact that the injured plaintiff receives only a paltry 28-30% of the actual premium dollars. Some say that figure is even lower than 28-30%.

Contrary to Dr. Maher's conclusion, there are legislative solutions. While they may not serve as a panacea to these complex problems, they can at least stabilize a most volatile and threatening insurance climate. Furthermore, changes in our tort system will help remove the litigation "Sword of Damocles" which currently hangs over the head of everyone who performs a service or who makes and sells a product. The tort or personal injury system has been abused to the extent that it has served as an instrument to pick the "deep pockets" of professionals, corporations and government. What some people fail to recognize is that these "deep pockets" eventually filter down to all of us.

Studies have indicated that savings can be achieved by structuring payments for larger awards as they do in lottery payments. Limiting contingency fees for lawyers will assure the plaintiff receiving more of the award and, if equitably done, will still guarantee lawyers an adequate amount for their efforts. A $250,000 limit on awards on pain and suffering, such as has been enacted and found constitutional in California and which has received strong support in public polls, is critical to an effective reform package. Such a cap would not in any way limit the award for economic damages, such as loss of income, medical bills or out-of-pocket expenses. Clearly something must be done.

With two million physician/patient contacts a day and ten million a week, there are bound to be some medical mishaps. But, as the record shows, many have come to mistakenly equate injury with negligence. As found by the 1973 Presidential Commission on Malpractice, we have "developed many unrealistic expectations about medicine's capabilities. . .and the failure to achieve ideal health has caused great disappointment with the results of treatment on the part of some patients and they have turned with greater frequency to the lawsuit as a means of resolving their disappointment."

This was not and is not to say that patients or consumers injured by negligence on the part of physicians or corporations should not be compensated. Those injured by negligence most assuredly should be reimbursed, but let us change the system so that they will receive the lion's share of the award.

Reinsurance is a major component of a dangerous liability crisis that literally threatens the very existence of future insurance availability. The average jury award of $166,000 in 1974 for medical malpractice cases has risen to $888,000 in 1983. The average product liability award in 1974 of $345,000 has increased to $1.7 million for 1984. This past year one private lawsuit was filed for every 15 Americans, up 50% from 1979. An estimated 16.6 million private civil suits were tried in the state courts and 150,000 in federal courts. The proliferation of liability suits in all sectors of our society must be arrested or it will not be only the cost of insurance premiums which has gone out of sight. Goods and services will soon follow if the insurance crisis is not halted.

Winston Churchill once said that "Americans can always be counted on to do the right thing, but only after they have exhausted all of the other possibilities." Many would suggest that we have exhausted all other possibilities with regard to the liability insurance crisis, and the time has come for a substantial overhaul of our toxic tort system.

Sincerely,
Timothy B. Norbeck

Executive Director
Connecticut State Medical Society

BOOK REVIEW

X-Rays: Health Effects of Common Exams.

By John W. Gofman and Egan O'Connor. 439 pages. Sierra Club Books, San Francisco, 1985, $25.00.

X-Ray exams are an indisputable part of the daily practice of medicine and dentistry. Every year American medical and dental patients receive a total of more than 300 million diagnostic X-Ray exams. This book evaluates the risk of cancers, leukemia, genetic and congenital injuries from these multiple exams and check-ups, and the side-effects from the X-Ray exposure. It deals with the common X-Ray exams, including C.A.T. Scans, fluoroscopies, and some common angiographies.

The authors state that the human evidence has convinced everyone who has examined it that ionizing radiation, even at low doses, produces an excess of human cancer, leukemia, genetic injury, and birth defects. There is no threshold or harmless dose, from five rads to lower doses, of ionizing radiation.

Physicians and dentists should be informed of the Twelve Common Misconceptions about Ionizing Radiation which are described in chapter two. Chapters 5 to 12 list the risk tables for cancer and leukemia resulting from the use of the common X-Ray exams. A few examples follow.

> The cancer risk from an Upper Gastro-Intestinal Series at age 25 is 1 in 544 for males and 1 in 638 for females. There is a progressive decrease with advancing years to 1 in 55,600 in males in 1 in 52,600 in females at age 55 or over.
>
> X-Ray exam of the lumbar spine, one AP, lateral and oblique view using a wide field at the age of 15 years is a cancer risk of 1 in 221 for males and 1 in 231 for females. With advancing years the risk is proportionately smaller and at age 55 years it is 1 in 33,300 for males and 1 in 28,600 for females.
>
> Mammography of the average breast, 6 cms. thick, at the age of twenty years is associated with the cancer risk of 1 in 1,502. The risk decreases with advancing years. At the age of 55 or older the cancer risk is 1 in 125,000.
>
> In dentistry a full mouth X-Ray at the age of 25 years has a cancer risk of 1 in 898 in men and 1 in 2,433 in women. The risk progressively decreases with advancing age. At 55 years or older the risk is 1 in 90,900 for men and 1 in 200,000 for women.

From under 15 to 54 years of age, medical diagnostic X-ray exams in the United States induce annually 33,177 cases of cancer in males and 32,683 in females. Dental diagnostic X-Rays for the same age group induce annually 8,386 cases in males and 3,373 in females. Combining medical and dental X-Ray exams in both sexes total 77,619 cases of cancer annually, or 2,340,000 during thirty years.

The authors believe that it is possible to prevent 51,000 cases of cancer annually. This spectacular result could be achieved without eliminating a single exam or its benefits. Simply reduce the average diagnostic X-Ray doses to one-third of their current level. It is technically simple and need not reduce the quality of the diagnostic information. Recent research data from the Mayo Clinic and Case Western Reserve reduced the risk of breast cancer more than 60-fold from thoracic spine exams by developing ways to reduce the X-Ray dose.

There are chapters which explain the cancer risk from fluoroscopy, the common angiography (cardiac, renal and hepatic), and C.A.T. Scanning. Also discussed are injuries to an embryo or fetus from radiation, and risks from the use of the contrast agents.

Chapter 11 describes the time sequence for leukemia and solid cancers. The Hiroshima-Nagasaki experience showed that the group's rate of excess leukemia resulting from the irradiation reaches its peak about 7.5 years later. The excess cases are virtually absent some 30 years following the exposure to ionizing radiation. By contrast, for the various solid cancers discussed in this book, the rate of excess cases peaks some 40 years following the radiation exposure.

The objective of the book is to make the best estimate about the risk of developing cancer, leukemia, and other health injuries as a result of diagnostic examinations. The authors stress that the judgment of whether or not an X-Ray exam is good for a particular person must be made by the physician with the full consideration of the risk from not having the examination.

This book is the only one of its kind. For the first time it makes possible to look up the magnitude of risks by age and sex from each of the 40 common X-Ray exams (mammography and dental exams included). It should be made available to all physicians and dentists as the PDR of radiography.

D.H. Fogel, M.D.

Greenwich, CT

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

REGARDING A MATTER OF INFORMED LEADERSHIP

To the Editor: At the semiannual meeting of the Connecticut State Medical Society House of Delegates held last fall, a resolution was considered regarding a requirement that county medical society officers, who are represented at a state level (such as at our Council), become members of the AMA. Unfortunately, the motion in favor of this resolution lost. I am writing to acquaint our members at large to the fact that I feel this matter should be reconsidered at a future meeting of the House of Delegates.

At last fall's semiannual meeting, I spoke to the issue in regard to both the philosophic and practical reasons why I feel that our medical leaders should be members of the AMA. The philosophic reason is because, if they are to do a proper job of leadership, they should be aware of what is happening on all sides of them, not only within our own state, but at a national level. The AMA regularly sends out legislative reports, AMA newspapers, and newsletters all aimed at keeping the membership advised in a very up to the minute fashion as to the direction of our own forces as well as the significant and ominous forces that surround us. Because this is a two way street, the AMA delegates and the AMA itself like to know the views of your leaders as to how they feel about the important issues regarding medical care and its delivery. When your county leaders report back to your general membership, they should be able to report eloquently on what is happening at a state and national level on such important matters as the malpractice crisis, Medicare freeze, restrictions and licensure, problems of financing graduate medical education etc., etc. As doctors interested in continued quality of medical care, you deserve no less than being aware of this.

In regard to the "practical" matter. It usually occurs that the state officers of the Connecticut State Medical Society (such as the president) are elected from the leadership from the county associations. Under recent rulings, the state society president can also be seated as an alternate delegate at the AMA. This obviously could not be done if such a member were not even an AMA member. Furthermore, should there be any temporary vacancy in the AMA delegation, the chairman of the Connecticut delegation is allowed to select someone from the county leadership to temporarily fill this spot at a national meeting. Again, this is considered a great honor that could come about only if one were an AMA member.

As physicians, we have become more and more aware of the importance of "informed consent". For this reason, we must insist on "informed leadership". The "rugged individual practitioner" is still most welcome on the scene but perhaps cannot stay on the scene for long unless he is fully cognizant of these many matters which heretofore he did not need to deal with. To quote John Donne: "No man is an island, entire of itself." If we fail in these matters, we shall certainly know "for whom the bell tolls."

Stewart J. Petrie, M.D.

Derby, CT

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New York Guidelines for Granting Medical Exemptions for Safety Belt Use

The New York State Vehicle and Traffic Law, amended in 1984, states that "no person shall operate a motor vehicle in New York State unless all front seat occupants are restrained by a safety belt." The law "shall not apply to a passenger or operator with a physically handicapping condition when the physical disability would prevent appropriate restraint in such safety seat or seat belt, provided however that such condition is duly certified by a physician who shall state the nature of the handicap as well as the reason such restraint is inappropriate."

The physicians of New York State have strongly supported the use of safety belts for many years, recognizing the fact that the mortality and morbidity incurred in motor vehicle crashes by unrestrained drivers and passengers are greater than by those properly restrained. Two decades of real world experience have proven that belts prevent or mitigate serious or fatal injuries by about 50%. In New York State, the use of safety belts could prevent an estimated 300-400 deaths each year. Additionally, some 72,000 injuries, many of these serious or disabling, would be avoided resulting in a $260 million savings annually in medical treatment and related costs.

Experience in countries where belt use is required has shown that less than 1% of all motor vehicle related injuries are *caused by* the belt per se, predominantly under conditions when an unrestrained occupant would be much more seriously injured.

The safety belt law provides no categorical, specific or routine medical grounds for granting a medical exemption. Each case should be decided on its own merit. If a medical exemption is granted, it should be issued for a valid medical reason.

Because of the benefits of using a safety belt, physicians should weigh very carefully the advantages of reducing the risk of injury or death to the patient who drives against any medical reason the patient may give for seeking an exemption from using a safety belt. If a person is fit to be in control of a vehicle, the evidence indicates that he or she is fit to wear a safety belt. Furthermore, physicians should be extremely reticent in granting medical exemptions to patients who are primarily passengers. If such patients are genuinely unable or decline to use a safety belt, they should be advised and strongly urged to ride in the back seat of the motor vehicle where it may be relatively safer to ride without a belt.

Physician's Liability

A physician granting a medical exemption may be held personally responsible for his action and should be prepared to defend the medical exemption in court. It is conceivable that physicians granting exemptions may be sued by unrestrained patients subsequently injured in a motor vehicle crash. For this reason, physicians are advised to keep a record of any medical exemption granted and the reason for it, the date it was granted and its expiration date if any.

An examination for a safety belt exemption is Medicaid-reimbursable when it includes a complete physical checkup (Code 90021). [Note: The Connecticut Department of Income Maintenance has *not* yet determined that seat belt exemption exams will be Medicaid-reimbursable.]

Some of the medical reasons that may be presented by patients for obtaining a medical exemption include certain musculoskeletal conditions and deformities, pregnancy, scars, pacemakers, ileostomies or colostomies, conditions of the breast, disabling conditions, unusual body size or shape, or psychological conditions. Many of the reasons presented result from lack of knowledge of the purpose and correct adjustment of the safety belt itself.

Musculoskeletal Conditions and Deformities

A correctly applied safety belt should not restrict the motion of patients with arthritis of the neck and shoulders while driving. If the rotation of the neck is limited and the trunk cannot be rotated while reversing the motor vehicle because of the safety belt, the patient should be informed that while not technically legal to do so, it would not be unreasonable to remove the safety belt when backing up.

Certain severe abnormal skeletal conditions such as rheumatoid spondylitis, ankylosed major joints, deformity or fusion of the spine or major joints, other gross musculoskeletal deformities, or orthopedic devices such as body casts, may make it impossible for the patient to fasten a safety belt properly. In such conditions, a medical exemption may be considered.

Disabling Conditions

Physically disabled persons permitted to drive with a restricted driver's license will benefit from the use of safety belts because of the stabilization provided by the restraints. The guidelines for musculoskeletal conditions and deformities also apply to physically disabled persons.

Scars

Well-healed scars present on the chest or abdominal wall are not harmed by a correctly positioned safety belt. Occasional irritation and pain have resulted from prolonged wearing of a safety belt, often too loosely positioned, allowing a certain amount of friction and movement over parts of a scar.

The New York Guidelines were endorsed by the CSMS Council on December 18, 1985, and they are the source of the Connecticut Guidelines released by the Department of Health Services and the Connecticut Safety Belt Coalition.

Recent tender or painful scars may require a foam pad taped to the skin over which the safety belt lies to prevent irritation and pain.

Pacemakers

Pacemakers are commonly implanted in the right upper part of the anterior chest just below the clavicle in about 85% of the patients and on the left side in about 15%. In general, safety belts do not cause discomfort to the pacemaker wearer or damage to the pacemaker itself.

If the pacemaker has been recently implanted and the surgical wound still painful, a foam pad may be taped to the skin overlying the pacemaker to prevent any irritation while the safety belt is being used.

Should the wearer of a pacemaker be involved in a motor vehicle crash and the pacemaker receive a direct blow by the safety belt, the wearer should as a precaution have the pacemaker checked by his physician for any malfunction. Such malfunctions, however, have not been observed clinically or experimentally.

Ileostomies and Colostomies

Ileostomies and colostomies in persons of average size and build do not interfere with the use of a correctly applied safety belt. Persons with ileostomies and colostomies who have been involved in motor vehicle crashes while wearing a safety belt have occasionally suffered irritation of the exposed mucosa with some bleeding and even tearing of the mucosa from the stoma wall caused by sudden constriction by the safety belt. Such injuries are relatively minor in comparison to what could be expected from not wearing a safety belt.

Conditions of the Breast

Breast irritation (mastitis) is rarely caused by belt use. When the safety belt is repositioned or the tension of the safety belt is reduced by use of a comfort clip or the "window shade" feature, the condition usually is resolved within a short time.

Pregnancy

Based upon research to date and experiences from countries with compulsory safety belt use laws, pregnancy no matter at what stage is not a valid reason for exempting safety belt use. In studies of belted pregnant women involved in motor vehicle crashes, it has been shown that there has been no increase in injuries to the fetus, or in fetal loss or abortion as a result of proper use of a safety belt.

Pregnant women should be instructed to position the belts correctly: the lap part should lie comfortably below the anterior superior iliac bones and the diagonal part across the costal margin, the sternum and clavicle. Thus, no part of the harness is allowed to compress the uterus.

Special Height or Weight Conditions

Persons five feet tall or less may complain that the shoulder harness safety belt crosses their neck, causing them discomfort. These persons should be referred to their car dealers for possible adjustment of the height of the seat, installation of a power seat, or the repositioning of the upper seat belt mounting point using a drop link. Adjustment of the position or tension of the safety belt with a comfort clip or the "window shade" feature may also help to alleviate the problem. Persons who are extremely obese and complain that the safety belt does not reach across their abdomen should be referred to their automobile dealers for modification of the existing belt, a safety belt extender or for the belt's replacement with a more appropriate one. If none of these alternatives are feasible, consideration may be given to granting an exemption.

Psychological Conditions

Patients manifesting severe claustrophobia can often be helped to accept safety belts by an explanation of the need and reasons for their use. A demonstration of the use of safety belts as part of the operation of a motor vehicle could serve to overcome such phobias.

Recommendations

- A medical exemption should only be granted for a sound medical reason and never routinely.
- A request for medical exemption must be carefully reviewed and all possible encouragement given to the patient to adapt the restraint system to the patient's condition (i.e., adjusting the position and height of the car seat, and adjusting and positioning the safety belt) before making a decision.
- If a medical exemption is granted, a record should be kept by the physician of the medical reason given by the patient for the exemption, the documentation of the basis for which the medical exemption was granted, the date it was granted and the expiration date if any.
- For temporary conditions, a medical exemption should be granted for periods of no more than 6 months, and renewed as necessary. For permanent conditions, a medical exemption should be granted for no more than 4 years and renewed as necessary.
- A patient who is primarily a passenger and who is unable or who categorically refuses to use a safety belt should be advised to ride in the back seat of motor vehicles.

Requirements

- A medical exemption may be granted only by a licensed physician.
- A certification of exemption for medical reasons must be issued on the physician's prescription pad or letterhead.
- The patient's name, date of birth and address, the date of issuance of the exemption, a clear statement of medical exemption from belt use and the doctor's signature must appear on the certification.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Emergency Physician, Norwalk Hospital. A progressive, 427 bed, Southwestern Connecticut hospital, seeking a physician with significant experience in Emergency Medicine, preferably Emergency Residency trained. We have an active service in which all Emergency Department Physicians are BC/BE. We operate our own paramedic ambulance corps. There is a separate primary care facility. Major affiliation with Yale University. Excellent compensation. Please send curriculum vitae, in confidence, to: Melvin D. Orlins, M.D., Chairman, Dept. of Emergency Medicine, Norwalk Hospital, Norwalk, CT 06586.

CONNECTICUT. 700-bed teaching hospital seeks Emergency Physicians who are board certified/prepared or who have strong Emergency Department experience to join ten Emergency Physicians with full department status. Hospital has strong university affiliation and strong commitment to Emergency Medicine, and offers competitive salary and fringe benefits including an exemplary child care center. The region has a rapidly improving EMS system and abounds in educational, cultural and recreational opportunities. Opening now or January 1. Send CV to Thomas Horrigan, M.D., Associate Director, Department of Emergency Medicine, St. Francis Hospital and Medical Center, 114 Woodland Street, Hartford, CT 06105.

Full time position in 260-bed Community Hospital in Southeastern Connecticut. Prefer emergency medicine or family-practice trained individual for busy ED with census of 40,000 per year. Excellent salary with full fringe benefits. Contact Gerald L. Springer, M.D., Chief, Dept. of Emergency Services, The William W. Backus Hospital, 326 Washington St., Norwich, CT 06360 (203) 889-8331.

Milford Hospital, a 150-bed J.C.A.H. recognized, full-service community hospital, located on the Connecticut shoreline is currently seeking an experienced Emergency Room physician. This full-time position offers a competitive starting salary and excellent fringe benefit package. Easily accessible by car, rail or air. Milford is a shoreline community of approximately 53,000. Submit resumes in confidence to: Monique M. Mauritz, Assistant Director of Personnel, Milford Hospital, 2047 Bridgeport Ave., Milford, CT 06460.

FAMILY PRACTICE

BC/BE residency trained to associate with same in Shoreline community. Excellent opportunity in a growing family practice leading to partnership after one year. Modern office, full hospital privileges, no Ob. Good coverage group. Excellent salary and benefit package. Please send curriculum vitae to CSMS, Box FP/JT.

Hartford area BC family physician seeks BE/BC associate to join well-established, expanding practice; partnership available. Attractive community of 60,000 located ½ hour from Hartford. A modern 250-bed hospital is conveniently located to the office. Coverage is readily available; no obstetrics. First year financial and benefits package available. Contact, Anne Sondek, Four-CS Vermont St., Buffalo, NY 14213 (716) 884-3700.

Family practitioner or internist for position in newly opened Family Center. Rapidly growing community 80 miles from New York City. Excellent salary/benefit package. Send CV to Alexander Isgut, M.D., 30 Church Hill Rd., Newtown, CT 06470.

Established, prepaid staff model HMO seeks an experienced board-eligible/certified family practitioner to staff our Wallingford Health Center. Unusual opportunity to meet the community's primary care needs where continuity of care, patient education/preventive medicine and high quality personal style are emphasized. CHCP has 42,000 members and is affiliated with Yale-New Haven Medical Center. Liberal benefit package. One opening available immediately, another starting July 1, 1986. Send C.V. and salary requirements to: Medical Director, Community Health Care Plan, Inc., 221 Whitney Avenue, New Haven, CT 06511. EOE M/F.

MISCELLANEOUS

Immediate position open full or part-time for physician for Ambulatory Care Center in Enfield, CT. Contact Robert S. Mausel, M.D., Medical Director, 15 Palomba Dr., Enfield, CT 06082 (203) 745-1684.

PEDIATRICS

Connecticut—BE/BC pediatrician with quality training to join solo practice close to Yale and University of Connecticut. Subspecialty interest welcome. Salary leading to partnership. Available July 1986. Please write to CSMS, c/o PED/SMF.

PHYSICIANS WISHING TO LOCATE IN THE STATE OF CONNECTICUT

DERMATOLOGY

Aug. '86. Age 50. Nat'l bds. AB cert. (PED); AB elig. (DERM). MD, Washington University in St. Louis; Int., University of Illinois Hospital; Res., Montreal Children's Hospital; Fellowship, Johns Hopkins Hospital (PED), Temple University, Skin and Cancer Hospital (DERM). Perfers solo, group or associate type practice in a large-sized community. Write, Aaron Glick, M.D., 5450 Wissahickon Ave., #848, Philadelphia, PA 19144.

FAMILY PRACTICE

Oct. '85. Age 39. FLEX. AB cert. MBBS, London University, Guy's Hospital; Int., Guy's Hospital, London and Farnborough Hospital, Kent, UK; Res., University Hospital, SUNY, Stony Brook, NY. Preference is to practice solo or with a group in a medium-sized shoreline community. Write, Patrick L. Neustatter, MBBS, 3216 Denton Dr., Merrick, NY 11566.

Available within 60 days notice. Age 33. Presently in practice. Nat'l bds. AB cert. MD, Int. and Res., Queen's University, Kingston, Ontario, Canada. Prefers a group practice with no obstetrics in a medium-sized community. Write, Lew H. Valliant, M.D., 115 Mountain View Dr., Elkins, WV 26241.

Sept. '86. Age 38. Nat'l bds. AB elig. MD, Temple University, Philadelphia, PA; Int. and Res., York Hospital, York, PA. Desires group type practice in a small to medium-sized community. Write, John (Sean) L. Barrett, M.D., 226 W. Jackson St., York, PA 17403.

FAMILY PRACTICE—Continued

July '86. Age 26. Nat'l bds. AB elig. MD, Hahnemann University, Philadelphia, PA; Int. and Res., Somerset Medical Center and Somerset Family Practice, Somerset Medical Center, Somerset, NJ. Prefers group or associate type practice. Write, James E. Barr, M.D., 207 Brooks Blvd., Manville, NJ 08835.

July '86. Age 28. Nat'l bds. AB elig. MD, Temple University School of Medicine, Philadelphia, PA; Int. and Res., Akron City Hospital, Akron, OH. Prefers group or associate type practice in a small to medium-sized community. Write, Carl G. Koplin, M.D., 2462 Eastlawn Ave., Akron, OH 44305.

GENERAL PRACTICE

Availability open. Age 45. Presently in practice. MD, Taiwan National Medical Center; Int., St. John General Hospital, Canada; Res., Victoria General Hospital, Canada; Fellowship, Col. Belcher Hospital, Canada. Prefers group, institutional or solo type practice. Looking for a position as a general physician with or without surgery. Willing to work in a state hospital or correctional medical institution. Write, Tom C. Ho, M.D., 1130-5 Street, N.E., Minot, ND 58701.

GENERAL/FAMILY PRACTICE

Jan. '86. Age 33. Presently in practice. Nat'l bds. AB cert. MD, S.U.N.Y., Downstate; Int. and Res., Geisinger Medical Center. Prefers solo, group or associate type of practice in a medium-sized community. Write Salvatore Perconte, M.D., 11 Sol Dr., Carmel, NY 10512.

INTERNAL MEDICINE

July '86. Age 28. Nat'l bds. AB elig. MD, Emory University; Int. and Res., Emory University affiliated. Prefers group or associate type practice in a medium to large-sized community and is interested in general internal medicine and intensive care. Write, Ronald S. Szabo, M.D., 812 Regency Woods Dr., Atlanta, GA 30319.

GASTROENTEROLOGY July '86. Age 32. FLEX. AB elig. MD, St. George's University School of Medicine; Int., Franklin Square Hospital, Baltimore, MD; Res., Union Memorial Hospital, Baltimore, MD; Fellowship, The Western Pennsylvania Hospital, Pittsburg, PA. Prefers associate, group or solo type practice in a medium to large-sized community. Write CSMS, ISG/IM.

July '86. Age 28. FLEX. AB elig. MD, University of Mississippi, Jackson, MS; Int. and Res., The Miriam Hospital, Providence, RI. Prefers solo, group or associate type practice in a small to medium-sized community. Write, Morris R. Hamilton, M.D., 12 Summit Ave., Providence, RI 02906.

OPHTHALMOLOGY

Nov. '85. Age 31. Presently in practice. Nat'l bds. AB cert. (PED); AB elig. (OPTH). MD, Chicago Medical School, Chicago, IL; Int. and Res., North Shore University Hospital; Fellowship, SUNY-Downstate Medical Center. Mostly interested in a group practice in general ophthalmology. Write, Andrew E. Gewirtz, M.D., 64 Pond Rd., Apt. G-3, Woodbury, NY 11797.

ORTHOPEDIC SURGERY

Anytime availability. Age 50. Licensed in Connecticut. Presently in practice. Quebec Orthopaedic Boards. MD, University of Ottawa, Ontario, Canada; Int., Fairview Park Hospital, Cleveland, OH; Res., Akron General Hospital, Akron, OH. Prefers solo, group, associate or industrial type practice. Write CSMS, BP/ORTHO.

PEDIATRICS

Immediately available. Age 34. Licensed in Connecticut. Nat'l bds. AB elig. MD, University of Arizona College of Medicine; Int. and Res., Phoenix Children's Hospital. Prefers a group type practice. Write, Nicholas J. Argyros, M.D., 544 Prospect Ave., Hartford, CT 06105.

Immediately available. Age 33. Presently in practice (part-time). Licensed in Connecticut. Nat'l bds. AB cert. MD, George Washington University School of Medicine, Washington, DC; Int. and Res., SUNY, Upstate Medical Center, Syracuse, NY; Fellowship, CT/Ultrasound and SUNY. Seeking locum Tenens, part-time or permanent position. Will consider any type of practice or size of community. Write, Douglas B. Bober, M.D., 47 Strawberry Lane, Manchester, CT 06040.

RADIOLOGY

July '86. Age 29. Presently in practice. Nat'l bds. AB elig. MD, SUNY Upstate Medical Center, Syracuse, NY; Int. and Res., University Hospital, SUNY at Stony Brook, NY. Prefers a group type practice in a medium-sized community. Has special training in Magnetic Resonance Imaging. Write, Brian J. Grogan, M.D., B-8 Lake Court, Middle Island, NY 11953.

Immediately available. Age 70. Licensed in Connecticut. Nat'l bds. AB cert. MD, Medical College of Virginia; Int. and Res., Beth Israel Hospital, Boston, MA; Fellowship, Pratt Diagnostic Hospital (N.E. Medical Center). Retired from Yale University. Seeking part-time activity or locum tenens. Write CSMS, SB/RAD.

SURGERY

CARDIOTHORACIC. Immediately available. Age 35. Nat'l bds. AB cert. MD, Albert Einstein College of Medicine, New York; Int. and Res., Alton Ochsner Medical Foundation, New Orleans, LA; Fellowship, University of Medicine & Dentistry of NJ. Prefers associate type practice. Write Dan Morgenstern, M.D., 8 Allwood Terrace, Livingston, NJ 07039.

SURGICAL ONCOLOGY. Jan. '86. Age 38. Nat'l bds. AB cert. MD, Int., American University of Beirut, Lebanon; Res., St. Luke's-Roosevelt Hospital, NYC; Fellowship, Memorial Sloan Kettering Cancer Center, NYC. Prefers group, associate or institutional type practice. Write, CSMS, c/o ASM/SUR.

July '86. Age 31. Nat'l bds. AB elig. MD, University of Connecticut School of Medicine; Int., Albany Medical Center Hospital, Albany, NY; Res., Albany Medical Center Hospital and University of Medicine & Dentistry of New Jersey. Prefers group or associate type practice in a large-sized community. Write, Richard Jay Karol, M.D., 15 Lyric Court, Towson, MD 21204.

SURGERY (GENERAL/VASCULAR)

July '86. Age 31. Nat'l bds. AB elig. MD, Rutgers University, New Brunswick, NJ; Int., Temply University Hospital, Philadelphia, PA; Res., Episcopal Hospital, Philadelphia; Fellowship, Lutheran Medical Center, Brooklyn, NY. Prefers solo, group or associate type practice in an average size community. Write, Lance A. Lieberman, M.D., 2046 76th Street, Brooklyn, NY 11214.

UROLOGY

July '86. Age 33. Nat'l bds. AB elig. MD, Boston University School of Medicine. Boston, MA; Int. and Res., Vanderbilt University Hospital, Nashville, TN. Experienced in adult and pediatric urology. Prefers group or associate type practice in a medium to large-sized community. Write, Ned R. Novsam, M.D., 8300 Sawyer Brown Rd., E-306, Nashville, TN 37221.

July '86. Age 30. Licensed in Connecticut. Nat'l bds. AB eligible. MD, University of Cincinnati; Int., St. Francis Medical Center; Res., Maimonides Medical Center. Prefers associate, group or solo type practice in a large-sized community. Write, Jonathan A. Waxberg, M.D., 950-49th St., Apt. 3F, Brooklyn, NY 11219.

Oct. '85. Age 33. Licensed in Connecticut. AB elig. MD, Autonomous University of Guadalajara, Mexico; Int. and Res., Downstate Medical Center, NY and Long Island Jewish Hospital, NY. Has had extensive Endourologic Training/Spanish Fluency. Prefers solo or group type practice in a medium to large-sized community. Write, Edward C. White, M.D., 5 Starlight Court, N. Babylon, NY 11704.

Patient Selection: Characteristics of the Hospice Patient

ROBERT P. ZANES, M.D.

The first step in establishing a set of standards to maintain a high quality of care in a Hospice program is a clear-cut definition of admission criteria. Some of these criteria are dictated by legislation, but the majority are established on the basis of understanding of palliative care vs aggressive care. The definition of palliative care varies from institution to institution. The guidelines which I will outline have been effective in our program at The Connecticut Hospice, but may be varied depending on individual community needs.

Three elements are essential in any program, whether home care or inpatient. One is that there be a terminal illness diagnosis confirmed. A second general rule is that there be approval of the selection and understanding of palliative care by the patient and the family. And thirdly, that this approval be given also by the primary physician. These three by definition necessitate an understanding by the patient and the family of the nature of the illness and in general terms, the prognosis. That understanding must also extend to the therapeutic needs of both patient and family. The physician must also be satisfied that no available curative measures are appropriate. This understanding is best provided by the primary physician as early as possible in the course of management of the illness and is essential as part of the discussion of a hospice referral with the patient/family.

The definition of "terminal illness diagnosis," with "a limited prognosis" must be thoroughly understood by the Hospice admissions process, by the Hospice care-givers, and by the patient/family and primary physician. The hospice staff person accepting the referral should quiz the primary physician specifically on this matter. These definitions include: (a) progressive metastatic neoplasia, in spite of therapy; (b) degenerative neurologic disorders; and (c) end-stage renal, hepatic, cardiovascular or respiratory disease, and therapy-resistant sepsis. The question may be asked of the referring physician as to what is the probable expected cause of death in some of the end-stage illnesses.

The attitude of the patient/family as a unit of care toward the goals of therapy for these disorders is extremely important in determining whether or not palliative care is appropriate. Individuals with degenerative neurologic disorders and with all those in category (c) may be kept alive sometimes for indefinite periods of time with life-support systems. If this is what the patient and family desire, they are certainly quite appropriate. A decision has to be made by the primary physician and by the patient/ family as to exactly what is palliative care and if that is the best course to follow. In the system at Connecticut Hospice, for example, respirators, intravenous fluids, and hyperalimentation are considered not appropriate for a person desiring palliative care only. In the Hospice setting time can be spent helping the patient obtain enough fluid intake in most instances to prevent symptomatic dehydration. Patients with metastatic cancer do not benefit significantly from nutritional support, so that the withholding of such is not a major factor in contributing to death. Many individuals do not understand this and careful discussion and agreement on all sides must be obtained before a decision not to continue intravenous fluids and hyperalimentation is made. We have had no problems with feeding tubes, whether gastrostomy or nasogastric since most of these individuals develop obstructive symptoms in the course of the disease which limits the amount of intake through the feeding tube. Ongoing discussion with the patient/family is essential in mutual appreciation of the disease process.

As a result of strict adherence to and open discussion with patients, families, and physicians on these criteria, more than ninety percent (90%) of our patients are admitted with a diagnosis of cancer in one

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ROBERT P. ZANES, M.D., Medical Director, The Connecticut Hospice, Inc. Former Chief of Hematology—Oncology Section and Director, Oncology Unit, Hospital of St. Raphael, New Haven; Associate Professor of Clinical Medicine, Yale University School of Medicine.

form or another. When the above issues have been decided there are other influencing factors on the need for Hospice care, either home care or in the inpatient setting. The first and foremost of these, of course, is the need for symptom control.

Sometimes, non-compliance or other reasons result in failure to control pain and other symptoms. We have found it effective to transfer the patient to an inpatient setting where more rigid control of doses, intervals, and other variants can be made. These admissions are sometimes very short-term and the patient returned home with the effective regimen.

Another need that requires transfer from home care to the inpatient setting may be for the final hours or days of terminal care. To some families the need for the patient to die at home is extremely great. Here the home care is invaluable. In other settings there is considerable discomfort about that occurring so the family and sometimes the patient, requests that this occur in the Hospice inpatient setting. The wishes of the patient and the family are always respected and prompt action taken whenever possible in these situations.

There are occasions when the patient's symptoms and debilitation have increased to the point where the family is totally emotionally and physically exhausted and is no longer able to provide adequate care for the patient at home. These individuals may be transferred to an inpatient setting for what is sometimes called "respite care." It has been our experience, however, that respite care to permit the family to conduct a few of the normal activities of daily living, free of constant pressures of a dying person at home, usually result from more rapid deterioration in the patient's condition, an increase in symptoms including pain, and therefore a marked increase in the patient's needs which make inpatient admission legitimate from other points of view.

Respite care, however, does serve an important purpose in strengthening the family's support system at this difficult time and may well result in easing of the bereavement process after the patient has died.

During the referral process it is extremely important that a knowledgeable representative of the Hospice staff, either a physician or a senior nurse, contact and speak personally to the referring physician. The information obtained from the original source of referral may be most inaccurate concerning diagnosis and prognosis and the true needs of the patient. This conversation also maintains a channel of communication with the referring physician which is extremely important, not only in the management of this individual case discussed, but in the future cases and keeping Hospice as an option in consideration of management of care of other terminally ill patients. That personal contact also permits the request for forwarding of medical records to be made. It is extremely important after the patient arrives in the hospice inpatient setting, or on the home care program, that adequate medical records be available for understanding and for optimum care.

Admission Criteria

Hospice Home Care and Inpatient

1. Terminal Illness Diagnosis;
2. Limited Prognosis;
3. Patient/Family/Primary M.D. understand palliative care and approve Hospice admission;
4. Further treatment to be palliative only;
5. Symptom Control—
   If a patient satisfies criteria #1 through #4 above, the patient may be admitted for control of pain or other symptoms which are not manageable in any other setting, anticipating a possible return home.

Definitions

Terminal Illness Diagnosis with Limited Prognosis:

a) Progressive metastatic neoplasia in spite of therapy;
b) Degenerative neurologic disorders (ALS, CVA, etc.);
c) End-stage renal hepatic cardiac or respiratory disease;
d) Qualifying features for (b) and (c):
   (1) No life support systems, e.g. hyperalimentation, respirators, I.V.'s etc.
   (2) probable expected cause of death known, in addition to primary diagnosis to justify prognosis -
   - renal failure
   - respiratory failure
   - cardiac failure
   - intractable sepsis

Comment: Any diagnosis in categories (b), (c), and (d) should be reviewed by admissions as possibly appropriate when patient and family specify a wish for palliative care and no aggressive diagnostic nor therapeutic means be employed.

Teaching Medical Students Patient/Family Involvement in Decisions

ROBERT U. MASSEY, M.D.

When I learned of the development of the first American hospice in New Haven, I visited Sylvia Lack to talk about the possibility of providing a clinical setting for medical student education in this new program. Later several of our faculty members, including Fritz Hinz and Jim Walker, met with her and others on the staff for fairly extended discussions about research and education in connection with hospice. Most of us felt that the attitudes and professional values inherent in the hospice concept were a perfect fit for some of the weaknesses, the omissions and commissions, which we perceived in the traditional clinical work of our medical students and residents. Here was a way to complement our medical education programs.

We were perhaps too early, both for hospice and for our curriculum planners as well, but we talked and learned; it became clear that we were considering not just another setting for clinical education, but rather a whole new set of skills and attitudes which had their origins in different philosophical premises from those which had come to underly 20th Century scientific medicine. Not radically different but not quite orthodox either; advanced medical technology in most of its forms developed from and serves to fulfill the caring obligation of medicine, but only as a way to meet part of that obligation. There is more to doctoring than tending the machine at the bedside. This is the lesson for our students to learn, or more likely they have already suspected it and our task is to reinforce and reaffirm, to assure them that it is all right for them to hang onto their idealism.

In the recent association of American Medical College's Report to the Panel on the General Professional Education of the Physician, "Physicians for the Twenty-First Century," the first of five conclusions refers to the matter of attitudes and values four times in its recommendations. This is new. These terms have not appeared in any of the earlier reports on medical education, as far back as the Flexner Report of 1910. I don't imply that the notion of values was considered irrelevant to the physician's education; rather I believe it was assumed that students engaged in the study of medicine would already have acquired "those skills, values, and attitudes that are the foundation of a helping profession." The 1984 GPEP report makes explicit these educational objectives which were assumed before. In their recommendation for the undergraduate preparation for medicine, the panel urges that education "encompass a broad study in the natural and social sciences and in the humanities."

Education in the humanities is a necessary but insufficient preparation for the understanding of the hospice philosophy. Nevertheless, to recapture for the student the idea of the physician as healer, the essential humanity of taking care of the sick while at the same time attempting to cure them, requires an understanding of our common cultural and religious heritage and an appreciation of its value in ordering our professional lives. It is not difficult for students to recognize the *ought* of medical practice as well as the *is* of medical science. This element of medical education has to do with the traditional role of the healer and the caregiver; it has to do with notions of balance and appropriateness, with human dignity and the rights of patients to manage their living and to indicate the place and manner of their dying; with attitudes toward mortality and even immortality.

The word *hospice* itself evokes literary associations having to do with hostelries and inns, with restored peace at the end of a journey. It is well to start there; the students will recall the comfortable humanity of some of the allusions:

> JOHNSON: "There is nothing which has yet been contrived by man by which so much happiness is produced as by a good inn."

Some will recall their childhood sadness when they

ROBERT U. MASSEY, M.D., Professor and Head of the Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

came to the line in St. Luke's Christmas Story: "and she brought forth her first born son,—and laid him in a manger; because there was no room for them in the inn."

The story of the Good Samaritan is perhaps the next place to stop. Someone has pointed out that we are not told in that parable whether the wounded traveler lived or died; that, it turns out, is not important. What takes place between the traveler, the Samaritan, and the innkeeper is the whole story, and the stage-setting is the road and the inn. It is a different story, but not totally different from the dramas which take place every day in our intensive care units. The distinctions and similarities, however, need to be talked about until they are recognized and accepted if our students are to understand the hospice philosophy and its significance for all of their work in medical care.

We need some history next. Our students need to know that modern medicine and public health are indeed the youngest sciences; that the patterns of illness with which they are familiar, the ways of death and dying which they have come to know, are unique to the latter two-thirds of the 20th Century. The progress in medical science and technology, the advances in public health, the revolution in biology have produced changes in human life like nothing which has occurred in history before our time.

There has been an inversion of mortality in the past 150 years, a compression of morbidity, a standardizing of death, and a consequent hiding of mortal illness in great bureaucratic institutions behind closed doors and unfamiliar machines. Our relation to these changes has not been entirely worked out; the technological imperative too often seems out of control.

"Things are in the saddle and ride mankind."

—Emerson

Our students need to recognize that this is a critical problem which they and their successors must handle; but for now, they may be helped to understand, by precept and example, that they can cut through the machinery and the bureaucracy directly to the patient, and that this is their first responsibility.

In his Annual Report for 1982-83, President Derek Bok of Harvard spoke of the need for reform in medical education. He noted that this need had been recognized for some time but that there was a remarkable resistance to systematic reform. He enumerated the forces which must finally compel changes. To many of us it has seemed that the principles inherent in the hospice idea if generally applied would help to move medicine and our medical institutions in the directions which for years society and our patients have been asking for. Let me review some of those:

1. The patient seeks first of all to be symptom free.
2. To have ready access to doctors and nurses in time of need.
3. To be assured of continuity of care.
4. To be respected as a member of a family whose members are also accepted and respected.
5. To be spared from isolation and loneliness.
6. To be served by a team of skillful, dependable, and caring people.
7. To be seen as a person with a disease.
8. To have someone help him to deal with the anxieties and concerns of those who are near to him.

Of course our patients want and expect scientific competence, thoroughness, efficiency, and moderate cost; but first they want care, a word which derives from the same root as *caritas,* or love. You will all recall the much quoted line from Francis Weld Peabody, "the secret of the care of the patient is in caring for the patient."

Our students understand quickly and are, being young and idealistic, anxious to blame the system, or to blame the individuals in it, for what they will come to see as shortcomings. They may even be too anxious to provide exemplary personal care to the neglect of the remarkable technical means at their disposal. We must help them to achieve balance, to engage with us in a reform of medicine and a reaffirmation of its traditional values while at the same time incorporating into practice as quickly as we can the new knowledge of biomedical research.

One of the things which hospice teaches is that patients may make choices about their medical care. Especially during the course of terminal illness where the point is reached when the half-way technologies have little more to offer. Patients and their families may say *no* to further diagnostic testing, to more mechanical life support, to another round of radiation or chemotherapy; they may say *no* and expect to be heard, and even more importantly may be assured that there are other ways of being cared for and that their physicians and nurses will not abandon them if they ask to be cared for by different means, or in a different setting. That in fact they will even participate with them in making their decisions.

There is so much for the medical student to learn about human biology; so much to understand about the pathophysiology of disease; so many skills to acquire to manage the complex technology of modern medicine, that he may find the consideration of the human needs of his patients more than he can bear. Add to that the noise of the bureaucrats and the entrepreneurs who are trying to control or to make a profit from the system, and the medical student may fall in easily with his resident or his attending physician who have found playing the role of technicians an easier way to cope in a system where neither the doctor nor the patient seems to have much to say about their destiny.

In a commencement address at the University of

Texas in Houston this past year, an eminent medical educator, Professor Jeremiah Barondess of Cornell, noted that "last year *Alpha Omega Alpha* sponsored a national student essay contest. The ground rules were broad—any nontechnical issue in medicine could be considered—and the response was encouragingly brisk. I was distressed to find that the commonest theme struck in the submitted essays was the negative quality of the medical student experience, and within this context one common thread was the emphasis on scientific fact, to the perceived relative neglect of the humanitarian, caring issues in clinical care."

Earlier Dr. Barondess had quoted Peabody as saying that "the great end (of medicine) is the human relationship between the physician and the patient." He noted that an informal poll of the house officers at Cornell had suggested that in their 10 or 12 hour day they have only about one hour of direct patient contact. Students and residents, pressed by all of the technical business of medicine, are finding precious little time for that "human relationship" which is the "great end of medicine."

Scientific medicine is heir to the 18th Century enlightenment, the humanitarian movement of the early 19th Century, the great advances in experimental biology of the late 19th Century and the 20th, the progressive era and the exponential technological advances of these recent decades. Our students have been nurtured in science and technology; their medical education comprises the learning of an incredible number of hard facts and the performance of difficult technical deeds. The end is the cure of disease; anything less is unreasonable and culpable defeat; death is failure.

As educators, our task is to help our students to see that science and technology are only part of our heritage, an essential but not sufficient support for the edifice which is modern medicine. We are so used to teaching our students the *facts* of pathophysiology and clinical medicine, and showing them what to *do* in this or that clinical situation, that we forget to talk about who they should *be*.

In his essay, "The Virtues In A Professional Setting," William F. May quotes T.S. Eliot, who, in response to a question about what to *do* in a certain instance, noted that "we face two different types of problems in life. In dealing with the first kind of problem, we may appropriately ask the question, 'what are we going to do about it?' but for another range of human problems, the only fitting question is not 'what are we going to do about it?' but 'how does one behave toward it?' " In other words, there are times when one can only *be* someone, when *doing* something would be uncalled for. In addition to dressing the traveler's wounds, it was essential to be the Good Samaritan.

Hospice has chosen an inn to express symbolically what it intends to be. In the OED, hospice, deriving from the latin *hospitium*, meaning both hospitality and an inn, is defined as "a house of rest and entertainment for pilgrims, travelers, or strangers—a home for the destitute or sick."

> "And now once more I shape my way through rain or shine, through thick or thin, secure to meet, at close of day, with kind reception, at an inn"—William Shenstone.

If we succeed in reminding our students, reaffirming their own deepest impulses and longings, of their duty to care as well as to cure, of their obligation to stand by, to relieve suffering, to counsel, to sustain, we shall find all eager response. Those of us who have tried know that.

In a recent column in *U.S.A. Today,* "what do we want doctors to be?," Jonathan Moreno wrote that families and patients seek someone whose "impulse is to save; failing that, to nurture; failing that, to comfort; failing that to help them to succumb to the inevitable."

BEHIND THE FACE OF HYPERTENSION

Drugs—Drug Interactions

ANNE MARIE STEITZ, M.B.A., R.Ph.

My topic is drugs or drug interactions and I thought what I would do is start off by just describing some of the situations, disease states, and other factors that will produce or enhance the potential for adverse drug reactions and/or drug interactions.

One of the first factors to take into account is the presence of disease states. Many of our patients, particularly in the hospice setting, have other disease states in addition to their cancer. The presence of these disease states can contribute in a significant manner to the occurrence of adverse drug reactions or drug interactions.

One of the major categories of disease states, or impairments, is the impairment of renal function which will significantly contribute to adverse drug reactions or interactions by diminishing the ability of the patient to eliminate drugs that are highly dependent on the kidney for their elimination.

The presence of a low serum albumin is also a very significant factor frequently encountered in our patient population. Based upon the patients' debilitated condition and their inability to eat, it is quite likely that they all have very low serum albumin levels. The presence of low serum albumin levels decreases the extent of protein-binding, leaving more free drug available to interact with receptors. The greater the free drug concentration, the greater the potential to produce adverse effects, enhanced drug response, or drug interactions.

Another situation which is frequently encountered in our setting and probably in yours is the presence of impaired hepatic function. This becomes very critical because most of the drugs used in symptom control regimens are metabolized by the liver to inactive compounds and then eliminated by the kidney. If the liver is not capable of doing this metabolic process, you're going to have an increased amount of active drug remaining and an increased potential for side effects and drug interactions.

Nutritional status can also have a significant effect on the incidence of drug interactions and adverse reactions. Poor nutritional status, the end result of which is electrolyte imbalances and more significantly low albumin levels, can affect free drug concentrations and, therefore, produce enhanced or adverse drug responses.

The final factor to consider is age of the patient. The aging process is associated with a number of physiological changes in the body that will affect a person's ability to handle drugs, and therefore will significantly affect the pharmacological response observed.

The elderly population is assuming an increasingly larger proportion of the overall population. In our hospice setting, about 75% of all patients admitted are over 65 years of age and as a result we must deal with this aging factor quite significantly in our day-to-day decisions regarding medication regimens.

Two of the very significant consequences of the aging process are disease and organ system changes. The older people become, the more prone they are to developing a number of disease states which affect their drug handling capabilities. Disease states such as hypertension, diabetes, atherosclerosis, emphysema, and congestive heart failure commonly seen in the elderly population will have some effect on drug selection and dosage regimen design.

In addition, there are actual changes in organ systems that occur as a result of the aging process. Most notable are the changes that have already been mentioned, i.e. a decrease in renal function, a reduction in hepatic function, and diminished blood flow to different organs in the body. All of these factors will have significant effects on the pharmacokinetic properties and therapeutic effects of certain pharmacologic agents.

So what we see as a result of the aging process are both pharmacokinetic changes (e.g. absorption, distri-

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bution, metabolism and excretion or elimination of drugs) and pharmacodynamic effects.

Pharmacodynamic effects relate to the change in receptor sensitivity which tends to occur as a person grows older. Most often receptor sensitivity is enhanced with increasing age such that an enhanced sensitivity to the effects of a drug are observed. This means that a lower dosage in an elderly patient will produce the same pharmacological effect as a usual or normal dosage would in a younger patient. Giving the usual dose to an elderly patient would result in an enhanced response and possibly an adverse effect. It is important to realize that even if there are no changes in the pharmacokinetic parameters of a particular drug that there can be changes in pharmacodynamic parameters which will affect the drug response achieved in an elderly patient. For example, the benzodiazepine class of anti-anxiety agents (e.g. Valium®, Librium®, Serax®, etc.) can produce an enhanced response in elderly patients because of the increased receptor sensitivity the elderly have to this class of drugs. Another example is oral anticoagulants such as Warfarin.® It seems that elderly people have an enhanced response to that drug as a result of increased receptor sensitivity and that may result in increased or excessive anticoagulation in certain patients.

On the other side, it seems that elderly people have a lessened response or a diminished receptor sensitivity to some drugs like propranolol (Inderal®) so that, perhaps, higher doses may be needed to produce the same therapeutic effect. Although, diminished receptor sensitivity can occur, it is observed to a lesser extent than enhanced receptor sensitivity in the elderly patient.

Age-related changes in pharmacokinetic parameters can significantly impact the pharmacological responses achieved in elderly patients. Absorption is a major pharmacokinetic parameter to be considered. In our patient setting about 92% of all the dosages are given orally, with an even greater percentage of doses being given orally in the home care setting. So it is very important for us to consider how well these drugs are absorbed by our patients. The G.I. tract undergoes a number of physiological changes as a person ages and these changes will have some effect on the ability to absorb drugs. One of these changes is an increase in gastric PH, that occurs because elderly patients tend to produce less gastric acid. This change in gastric PH may be significant for those drugs that are absorbed in the stomach and require an acidic environment for optimal absorption. An example of this would be iron. Iron is absorbed much better in an acidic environment. The higher the PH, the less acidic the stomach environment and a lesser extent of absorption of iron can be observed.

Another example of a drug whose absorption is affected by gastric acidity would be penicillin. The absorption of penicillin would be enhanced as gastric PH increases because less of the penicillin would be degraded in a less acidic environment. In other words, penicillin is inactivated in the presence of acid. If you have less acid, the penicillin will be intact and be more likely to be absorbed.

A second factor affecting absorption is the reduction in G.I. blood flow. What tends to happen is that cardiac output diminishes as people advance in age. Blood flow to different organs is reduced as a result of diminished cardiac output. A 40 to 50% reduction in blood flow to the G.I. tract is observed in the elderly patient. A reduction in G.I. blood flow can result in a lesser extent of absorption. The clinical significance of this finding has not been demonstrated. However, it is important to keep this factor in mind.

In addition to altered blood flow, there is a reduction in the number of cells capable of absorbing drugs in the G.I. tract. However, the clinical significance of this age-related change has yet to be determined.

One of the more important effects resulting from advancing age is a decrease in G.I. motility. The motility of the G.I. tract slows down such that the passage of drugs through the G.I. tract is slowed. As a result, there could be less drug absorption associated with a reduction in G.I. motility. There is a greater opportunity for drugs to bind with other contents in the G.I. tract, and thereby be inactivated or rendered unabsorbable. On the other hand, there may be enhanced absorption for other drugs, especially those that are usually poorly or slowly absorbed. By slowing the transit time through the G.I. tract, you are giving the drug more time to be in contact with the cells that are absorbing the drug. But, again, there is not a great deal of evidence to suggest that this is clinically significant with particular agents.

A final factor is the increase in the gastric emptying time and this relates somewhat to the motility factor. With an increase in aging there is a decrease stomach motility and thereby an increase in the amount of time it takes for the stomach to empty its contents into the small intestine where most of the drug absorption occurs.

Increased absorption for drugs that are absorbed through the stomach could result. By slowing down the gastric emptying time and thereby increasing the amount of time that the drug spends in the stomach, there is the potential for better absorption. Some examples of drugs whose absorption is enhanced because of an increase in gastric emptying time are lithium, riboflavin and nitrofurantoin.

For other drugs, a decrease in absorption may be seen. For drugs that are very sensitive to the acid environment, it is quite possible that increased gastric emptying time will allow for additional acid degradation and result in a lesser degree of absorption.

Some examples of drugs affected in this manner are cephalosporins, thiamine, penicillins and erythromycins.

In conclusion, there is not a lot of information that says how clinically significant these age-related changes in absorption are, but I think it is important to keep them in mind as you approach drug regimen selection and design in elderly patients.

There are many more significant pharmacokinetic changes that occur with advancing age. Drug distribution is significantly affected by the aging process. Distribution refers to the ability of the drug to be distributed to various organs and tissues within the body. Drug distribution follows absorption, and there are a number of factors which will affect the ability to distribute the drug. Much of the distribution process depends upon the actual physical chemical properties of the drug. Some drugs are by their chemical nature very well distributed. These drugs readily distribute throughout the body and central nervous system. Other drugs cannot be extensively distributed because their structural characteristics preclude this. There are some changes that occur in the aging process that will have some impact on their distribution, nevertheless.

One of the very important changes which occurs with the aging process is an overall change in body size. In general, elderly people are of smaller physical stature than younger healthier individuals. This is attributed to an age-related reduction in size and height, probably due to softening and compression of the spinal column and a loss of muscle tissue. Using standard or usual doses may not be appropriate in an elderly person because they are so much smaller and do not have the same volume of distribution as a younger individual. Dosage reductions are often required in the elderly to compensate for this change in body size.

But even more significant than this is that there are some changes in the composition of the body which will significantly affect the distribution of certain drugs. One of the changes to be considered is the change in the total body water compartment. This is a body compartment in which many drugs distribute and is represented by the amount of body water that each person contains. This is reduced by as much as 15% as one advances to the more elderly ages of 70 or 80. Giving usual or standard doses to the elderly patient can be problematic because of the higher drug concentration achieved when there is a smaller distribution volume. An enhanced pharmacologic response or toxicity otherwise known as an adverse drug reaction, can result if appropriate dosage adjustments are not made.

Another age-related change occurs in lean body mass, which is represented by muscle tissue. It seems that in proportion to overall body weight, lean body mass is also reduced as one ages. Drugs that are primarily distributed into the volume represented by lean body mass will have increased blood levels if no dosage adjustment is made in light of this factor. A classic example of drugs affected by changes in lean body mass are the aminoglycoside antibiotics (e.g. gentamicin, tobramycin).

An important consideration, particularly in our setting, is the amount of adipose or fatty tissue which elderly people usually possess. Contrary to what you would think, there is an increase in total body fat that occurs with increasing age. Interestingly enough, it happens to a greater extent in the male than in the female. This becomes important for those drugs that are very fat soluble, or lipophilic. The adipose tissue serves as a reservoir for fat-soluble drugs. With an increase in adipose tissue there is greater distribution of drug to this reservoir. This produces a lower serum drug concentration yet a more prolonged drug effect with many fat-soluble agents. The sedative-hypnotics like diazepam or pentobarbital are very fat soluble agents. Not only are elderly people more sensitive to the effects of these drugs, but because they have a larger fat store for these drugs to distribute to, they are more likely to experience residual effects such as drug hangover due to gradual leaching of drug from the fat reservoir many hours after a dose is given.

Another example, perhaps closer to us, is methadone (Dolophine®) and levorphanol (Levo-Dromoran®), two relatively fat-soluble narcotic analgesics. Both of these drugs have extended half-lives, and are extensively distributed to the fatty areas which will form a reservoir for these drugs to accumulate in. Accumulation of these agents over time can result in hallucinations, disorientation and confusion in the elderly patient.

Another significant change that occurs with the aging process that affects drug distribution is a change in protein-binding capability. Drugs that are bound to a protein cannot exert any pharmacological effects. A drug must be free of protein in order to bind with the receptor and produce a pharmacologic effect. So, as you can imagine if you have less protein available to which a drug can bind, and it is a very highly bound drug normally, more free drug will be available to interact with receptor and produce either the desired, or if in excess amount, the undesired response. Elderly people are known to have reduced albumin levels. Albumin is the primary protein in the body which binds drugs. A reduction in serum albumin can produce adverse consequences if highly protein bound drugs are given in usual doses.

There has been a lot written about the drug interactions which can occur when you give the patient two highly bound drugs at the same time. There are a lot of drugs that are very high protein bound (e.g. warfarin, barbiturates, phenytoin). Using highly protein-bound drugs in combination can cause drug displacement and possibly, thereby, an enhanced response or toxicity. The concomitant use of two highly protein bound drugs in an elderly patient can be somewhat dangerous if dosage reductions aren't made to reflect the reduction in protein binding capability.

Another change that can effect the distribution of drugs is, as I mentioned earlier, the reduction of blood flow that occurs as a result of decreased cardiac output. This will decrease the rate of delivery of drug to either the organ where it is going to exert its effect or to one of the metabolic organs which is going to be responsible for its elimination. This can have some impact on the design of your dosage regimen.

Unfortunately, there is no way of prospectively determining which patients are going to experience this effect and to what degree. There is no quantitative measure of changes in drug distribution which can direct dosage regimen design. However, this information serves as background material with which you should approach the use of drugs in elderly patients.

Metabolism is the third pharmacokinetic parameter affected by the aging process. Liver function is diminished in an elderly patient and there are three factors which contribute to this reduction in hepatic function. One, which becomes very important for drugs that are very highly metabolized by the liver, is the decrease in blood flow to the liver itself. A reduction in blood flow produces a reduction in the delivery of the drug to the liver where it is going to be metabolized. There is a 40 to 50% reduction in the liver blood flow associated with advancing age. Some drugs that would be affected by this are drugs like propanolol and lidocaine that are heavily metabolized by the liver and require a good blood flow to the liver in order to be eliminated.

Another factor which has been postulated is that the mass of the liver is reduced in size as one ages. Although this seems reasonable, there has not been any way of quantifying this or confirming that this contributes in a significant way to the overall changes that are seen in hepatic function in the elderly patient.

The third factor responsible for the age-related reduction in liver function is a decrease in hepatic enzyme activity. With age, certain enzymes within the liver become less able to metabolize drugs. The liver possesses two major metabolic systems responsible for drug elimination. Phase I metabolic activity represents oxidative types of reactions and the enzymes responsible for these types of reactions are much more affected by the aging process. In other words, an elderly person is much less able to oxidize drugs.

The other metabolic system is known as Phase II biotransformation, which involves the conjugation of drugs with substances like glucoronic acid rendering them more soluble and more readily eliminated by the kidney. Apparently, these Phase II metabolic reactions are less affected by the aging process.

Some examples of drugs undergoing Phase I biotansformation reactions are drugs like theophylline, diazepam, chlordiazepoxide, flurazepam, imipramine and quinidine. All these drugs require extensive metabolism to be eliminated from the body.

The Phase II metabolic transformation processes which represent conjugation reactions are less affected by the aging process. Some drugs which would be considered in this category are drugs like oxazepam (Serax®). This is why this drug is a particularly good choice in the elderly patient. It is not as dependent on the liver for its metabolism and, therefore, will not linger in the body for long periods of time and produce adverse effects. Other drugs are temazepam (Restoril®) and metoprolol (Lopressor®).

It is also interesting to note that there are a number of substances which, when ingested in any population of patients, will induce liver enzymes to metabolize more rapidly. Things like caffeine, alcohol, barbiturates will enhance the liver's capability to metabolize drugs. It seems, however, that elderly people are much less susceptible to this enzyme induction. It is important to keep this in mind.

Although we know a lot about the physiological changes that occur with advancing age and some of the changes in liver function which may result from that, we have no way of quantifying it. Liver function tests will tell you that there is some liver impairment but there is no way of correlating the results of those tests with the dosage reduction that is needed. This is one of the difficulties that we have. A trial and error approach or just an empiric adjustment of dosage is the best we can do.

The last pharmacokinetic parameter to be considered is elimination. This is another pharmacokinetic process which is affected by the aging process. Elimination refers to renal excretion of drugs. The ability of the kidney to excrete certain drugs is diminished with increasing age. Some examples of drugs that are affected by decreased renal excretion are digoxin, lithium, aminoglycosies, procainamide, penicillin, cimetidine and the thiazide diuretics.

There are a number of factors which contribute to the reduction in renal function which we observe in elderly patients, and one is a reduction in renal blood flow. The age-related reduction in cardiac output that affects the liver and distribution of drugs will also affect the blood flow to the kidney, and therefore, the ability of the kidney to eliminate a drug. Probably more important though, is a reduction in the glomerular filtration rate. Most drugs are filtered by the glomerulus part of the kidney. This filtration capacity is diminished significantly with advanced age. The elimination of certain drugs (e.g. aminoglycosides) is very closely related to the ability of the kidney to filter through the glomerulus, so that diminished glomerular filtration rates will result in a limited ability to eliminate drugs.

Fortunately, there are ways of quantifying changes in renal elimination which can be extrapolated to dosage requirements. There are numerous nomograms which permit calculation of creatinine clearance from a single serum creatinine value. Creatinine clearance provides a good representation of a patient's ability to eliminate a drug and therefore will allow for optimal dosage regimens to be designed.

The third factor contributing to age-related reductions in renal function is the decrease in tubular secretion of drugs observed in the elderly. This is significant for drugs that are highly secreted by tubular mechanisms, a good example of which is penicillin and its derivatives.

In summary, there are a number of age-related changes in physiological function which will affect a patient's ability to handle drugs. An awareness of the changes in pharmacokinetic and pharmacodynamic factors associated with the aging process will assist the clinician in drug and dosage selection which will minimize the incidence of adverse effects.

Pain and Symptom Control: I

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Historical Background

In Ancient times, pain was believed to result from demons or fluids that entered or were inserted into the body. The practice of cupping or blood letting arose from attempts to treat pain by freeing the offending spirits. About 300 B.C., Aristotle theorized that the heart was the "sensorium commune," the area of integration of all sensation. He described pain as a passion of the soul and he believed sensations were painful when their sensible extremes, such as acid and sweet, were in excess. We preserve some of this thinking in modern times by recognizing pain as a somatopsychic experience, that is there always is an element of passion.

Descartes in the 17th Century, formulated the Specificity Theory of Pain in which he postulated that every painful stimulus activates a specific pain receptor in the skin. Each receptor was connected by a unique thread running up through the central nervous system to the brain. As soon as a receptor was triggered, the message would be signalled to the brain where an appropriate response was elicited. Each painful sensation had a specific receptor, sensory pathway, and area in the brain associated with it. Qualitative differences in pain sensation were difficult to explain other than assuming a direct quantitative relationship between the numbers and types of receptors being stimulated and the resultant perception of pain.

The Intensity Theory of Pain proposed by Webster and Erb, as well as a similar version by Sheider in the 19th Century, stated that every sensory stimulus is capable of causing pain if it achieves a certain threshhold of intensity. It was similar to the Specificity Theory of Descartes except that qualitative differences in pain were explained by changes in intensity of the painful stimulus detected by pain receptors rather than quantitative numbers of pain receptors being triggered.

There are several shortcomings with these simplistic theories. They do not adequately explain qualitative differences in pain appreciation and pain-related behavior, nor do they explain the origin of pain from structures without pain receptors such as deafferentation pain arising from nerve injury or transection. Examples of phenomena not explained by these theories include; (1) the absence or minimal perception of pain in soldiers severely wounded in battle; (2) pain-

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related behavior which persists despite cessation of a pain-inducing stimulus; (3) the presence of pain in the absence of apparent physical injury or when nerves are compressed or transected.

In the first example, the above theories cannot explain why a soldier's perception of pain should change with his environmental surroundings. According to these theories, the soldier should feel as much pain due to injury whether he was on the battlefield or whether he was at home because pain receptors are being stimulated to the same degree in either case. In the second example, persistent pain-related behavior cannot be explained. A rat trained to move off an electrified grid each time a bell rings will persist in this behavior even when the grid is no longer electrified. The above theories cannot explain why pain-related behavior persists despite the lack of a painful stimulus. Lastly, these theories cannot explain the origin of tic doloreaux pain or phantom limb pain. In these conditions there is no apparent physical injury to nerves and pain seems to arise from nerves themselves which have no pain receptors. These theories cannot explain the origin of pain in structures which do not have specific pain receptor innervation.

The shortcomings of the above pain theories suggest that in order to have validity, a pain theory has to adequately explain why pain perception and pain-related behavior do not have a simple cause and effect relationship to a painful stimulus. It also has to explain how pain can be modified by physiological responses to stress as well as other factors such as a person's expectations, past pain experiences, and learned behavioral responses. In addition, a pain theory has to adequately explain how pain can originate in structures other than those innervated by specialized pain receptors such as the pain arising from direct nerve injury or compression.

Definitions

Pain is difficult to define because it is an inherently subjective experience. However, a good operational definition is that proposed by the Subcommittee on Taxonomy of the International Association for the Study of Pain. Their definition of pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage."

The *sensation threshhold* is the minimal stimulus intensity needed to cause a sensation. This is constant in all cultures.

The *pain threshhold*, defined as the minimal intensity needed to induce pain, is variable between individuals and cultures.

The *pain tolerance level* is the maximal stimulus intensity causing pain that a person is prepared to tolerate. This is also variable between people and cultures, with some cultures being much more tolerant of pain than others. The differences in pain tolerance level and pain threshhold in different cultures, suggest that there is a modification from higher centers of pain-related behavior in terms of how one reacts to pain.

Neuro-Anatomy and Neuro-Physiology

At this point, a brief review of the neuro-anatomy of pain transmission is appropriate. First order peripheral afferent neurons ending in nociceptors, detect painful stimuli in somatic and visceral tissues. The first order neurons transmit their messages to second order neurons in the dorsal horn of the spinal cord. Second order neurons cross the spinal cord and ascend to third order neurons in the brain stem and thalamus which then synapse on fourth order neurons in cortical somatosensory areas. Some of the first order neurons also synapse on interneurons in the spinal cord. These interneurons may stimulate other neurons in the spinal cord which then ascend to the level of the thalamus and brain stem. Some of the interneurons synapse on anterior horn cells and initiate local reflex responses (deep tendon reflexes) while other interneurons may synapse back on the first order neuron participating in a biofeedback inhibitory system.

At the levels of the brain stem, thalamus, and cerebral cortex, there are multiple interconnections between the limbic system and pain pathways, presumably having to do with the emotional response to pain. In addition, there is a descending system originating in cortical areas and the brain stem which modulates pain transmission by inhibitory mechanisms. In summary, painful sensations are conducted by an ascending system originating in peripheral pain-sensitive structures and ending in the brain stem, thalamus, and ultimately the cerebral cortex. This system is modulated by a descending system originating at suprasegmental levels (somatosensory cortex, limbic system and brain stem), as well as at segmental spinal cord levels (interneurons participating in negative biofeedback mechanism).

Peripheral sensory receptors can be divided histologically into two types. The majority of nociceptors (peripheral pain receptors) consist of bare nerve endings. Other categories of sensory receptors which can record pain include thermoreceptors, chemoreceptors, and mechanoreceptors. However, it is the nociceptors in peripheral tissue that most often are triggered by painful stimuli.

Nociceptors are usually activated by compression or by various bioactive chemicals. Compression can be present at the nerve ending itself or anywhere along the course of the afferent nerve. A temporary compression induces a transient impulse. A persistent compression induces an on-going discharge in the afferent nerve which can produce parethesias and modified pain. A second and probably more common cause for nociceptor excitation is chemical excitation. Many stimuli induce the synthesis or release of chemical substances from injured tissue, e.g. potassium ions, A.T.P., histamine, bradykinin, prostaglandins, and serotonin. Small amounts of these substances may not initiate pain, but they may sensitize tissues to other stimuli lowering the pain threshhold. Larger quantities of bioactive chemicals can of themselves induce pain impulses.

The two principle nociceptor nerve fibres are the A Delta and C fibres. The A Delta fibres are slightly larger, myelinated, rapidly conducting fibres which respond to light or heavy pressure, temperature changes, and chemicals. They quickly convey information about the type of stimulus and help to localize it. The C fibres are smaller, unmyelinated, and are slowly conducting. They mainly convey information about the temporal characteristics of the offending stimulus, i.e. whether a stimulus is short-acting or continual. They also convey some information about the nature of the stimulus (hot or cold), but are poorly localizing. The majority of the peripheral pain fibres are C fibres.

In the late 1960's Melzack and Wall hypothesized the "gate theory" of pain modulation. They postulated this theory after studying the substantia gelatinosa in the dorsal horn of the spinal cord. They noted that first order nociceptive pain fibres enter the substantia gelatinosa of the spinal cord and synapse on interneurons and "pain transmission cells." The pain transmission cells then conduct stimulating impulses up the spinal column to the brain stem, thalamus, and cortex. At the same time they noted inhibitory systems. Non-nociceptive A Beta fibres when stimulated peripherally, inhibit the transmission of pain by activating inhibitory neurons which synapse on pain transmission cells and prevent them from depolarizing. The effects of transcutaneous nerve stimulation are explained by the gate theory of pain as follows: the external electrical stimulus activates A Beta fibres which in turn activates inhibitory interneurons in the spinal cord. These interneurons synapse on pain transmission cells effectively closing the gate to pain transmission.

Melzack attempted to clinically look at some of the things that alter pain perception. He looked at a number of modulating factors originating from higher cortical centers and compared them between people of diverse cultures, different personalities, and different past pain experiences. He observed that various factors can modify pain perception presumably via descending inhibitory projections. These included levels of anxiety and expectation, and levels of attentiveness. Melzack noted that pain perception could also be modified by simulation of internal organs and the autonomic nervous system.

In 1982, Melzack and Wall modified their theory by postulating additional modulation from suprasegmental levels. They surmised that pain transmission is not only modulated at a segmental level as noted above, but also at suprasegmental levels by descending neurons. The suprasegmental descending fibres synapse on inhibitory interneurons in the spinal cord, acting in a similar manner as the A Beta fibres. The descending inhibitory system was presumed to originate in the brain stem as well as hypothalamus, somatosensory cortex, and limbic system.

Neuro-Chemistry

The actual mechanism of pain modulation in the spinal cord probably occurs in a number of ways. Stimulation of peripheral nociceptor fibres results in the release of substance P, a neurotransmitter in the dorsal horn of the spinal cord.

Normally, this neurotransmitter would stimulate the "transmission cells" which would then send impulses up the spinal cord to higher pain centers. At the same time, some of the descending inhibitory fibres synapsing in the dorsal horn of the spinal cord secrete serotonin which inhibits the release of substance P. Other neurons in the descending inhibitory system synapse on interneurons in the dorsal horn stimulating the release of enkephalin. Enkephalin again inhibits the release of substance P. Lastly, A Beta peripheral nerve fibres may have also been activated, stimulating inhibitory interneurons synapsing on A Delta and C fibres. The transmission of pain, and therefore its characteristics, are thus determined by a balance between excitatory nociceptor input and inhibitory segmental and suprasegmental input. The mechanisms of pain modulation at higher levels are not well understood.

The presence of enkephalin and substance P as neurotransmitters in the spinal cord have been noted. A number of other substances can act as, or are suspected of being neurotransmitters. One of the more important ones is serotonin which is present in the descending pain modulating pathways. This is of interest because in some depressed individuals, serotonin levels are reduced. Depressed patients may experience pain more intensely in part because serotonin levels are reduced, resulting in less inhibition of pain transmission. In addition, the trycyclic antidepressants have been noted to be useful as primary analgesics and may in fact be acting by increasing serotonin levels in the central nervous system.

The ascending pain pathways were largely worked out in the 1950's. It wasn't until the 1970's that the descending pathways for pain transmission were clarified. In 1969 and 1970 Dr. Reynolds in Windsor, Ontario, discovered that if you electrically stimulate the periaqueductal grey area in the medulla you inhibit the perception of pain effectively producing analgesia. This led to the elucidation of descending inhibitory pain pathways, which at present are not known in as much detail as the ascending pathways. One of the better known descending pathways is that which arises in the periaqueductal grey area in the region of the 4th ventricle, and in the nucleus raphe magnus in the reticular formation of the brain stem. The probable sequence of events is as follows: Neurons from higher centers descend and synapse in the periaqueductal grey area. Enkephalins, endogenous opioid agonists, are released from these higher order neurons and stimulate cells of the periaqueductal grey. The periaqueductal grey cells then project to the dorsal horn of the spinal cord and release serotonin. Serotonin stimulates the inhibitory interneurons in the dorsal horn to release enkephalin which at segmental levels acts to inhibit A Delta and C fibre depolarization.

Neuro-Pharmacology

Opiate receptors are stero-specific proteolipids, with a chemical and physical configuration stimulating a lock and key effect with opiate substances. They are present at several levels in the central nervous system (spinal cord and brain). There are five classes of opiate receptors, the most common being the Mu receptor. The Mu receptors have a high affinity for morphine, opiates, and enkephalins and are related to supraspinal analgesia. Other opiate receptors (Kappa, Sigma, Delta, and Epsilon) are related to non-analgesic effects of opiates such as sedation and psychomimetic effects. Morphine preferentially binds Mu receptors. However, when Mu receptors become saturated, morphine will bind other opiate receptors and produce effects other than analgesia. Other narcotics bind non-Mu opiate receptors to a greater or lesser degree than morphine, resulting in various undesirable effects. The ideal opiate of the future will be one that binds selectively only opiate receptors mediating analgesia.

Narcotic analgesics currently fall into three classes by virtue of how they interact with opiate receptors. The majority of them are morphine-like agonists or partial agonists. They are bound by opiate receptors and will produce analgesia. Naloxone, a pure opiate antagonist, will bind opiate receptors and block the effects of morphine, or morphine-like agonists or partial agonists. The third group of narcotic analgesics are drugs of the mixed agonist-antagonist class. These drugs have some analgesic action, but they also can antagonize the analgesic action of opiates. Pentazocine (Talwin®) is the prototypic agonist-antagonist. It probably has a high affinity for Sigma receptors resulting in it common association with psychomimetic undesirable effects. When administered prior to the use of another narcotic, pentazocine will produce analgesia. However, when given simultaneously with another narcotic or in place of a previously administered narcotic, pentazocine diminishes the analgesic effect of the narcotic, or may precipitate frank narcotic withdrawal.

The recognition of opiate receptors in the central nervous system led to the discovery of endorphins (*endo*genous *morphine*-like neuropeptides). Endorphins are bioactive neuropeptides which bind to opiate receptors and are implicated in the modulation of pain. Endorphins are derived from the degradation of long-chain lipoproteins, which are largely produced in the hypothalamic-pituitary axis. Beta-endorphin is derived from beta-lipo protein which is also the parent neuropeptide of beta-MSH and ACTH. Beta-endorphin is present mostly in the periaqueductal grey regions of the brain stem. (It is interesting to speculate about the relationship of ACTH and beta-endorphins with regards to responses to painful stimuli in times of stress, e.g. relative analgesia in soldiers wounded in battle.)

The enkephalins are pentapeptides that also act as opioid agonists. Their sequence of five amino acids is found within the enkephalin and beta-lipotropin structure. Enkephalins are found throughout the central nervous system including the dorsal horn of the spinal cord, periaqueductal grey, thalamus, mid-brain, and limbic system. They are believed to act in a similar fashion to the endorphins in that they modulate transmission of pain by stimulating opiate receptors on neurons in the pain transmission pathways. This prevents the depolarization of these neurons and therefore, the transmission of pain.

Neuro-Behavior

Lastly, I would like to touch on some aspects of pain and pain-related behavior. The brain has the capacity to undergo functional modification when excited by repetitive stimuli, i.e. learning. This presumably is mediated by creating preferential sets of pathways and synapses which respond in an automatic fashion to fixed stimuli. In this manner, complex behavior can be performed in a reflex or patterned fashion. The same patterning of behavior may occur in patients experiencing chronic pain and, result in pain-related behavior which persists despite the reduction or elimination of pain. This may partially explain some of the mechanisms of phantom limb pain and post-cordotomy pain. The mechanism of patterning is unclear although chronic pain may result in hypersensitivity of pain pathways which persists after the painful stimulus has ceased. As eluded to previously, pain-related behavior can also be affected by culture, past pain experiences, attentiveness, anxiety, expectation, and underlying personality.

Summary

Pain is an unpleasant experience or emotion resulting from actual or potential tissue damage. It is mediated by the peripheral and central nervous system by ascending pathways, and modulated by suprasegmental and segmental pathways. Neurotransmitters such as substance P, serotonin, enkephalins and endorphins are responsible for endogenous pain transmission and modulation. Opioids and other exogenous drugs affect these neurotransmitters and can modify pain perception. At this point in time, we do not have drugs which are specific for opioid analgesic receptors. Other mechanisms of pain control only briefly mentioned include transcutaneous electrical stimulation and oblation of pain conducting pathways (cordotomy, or thalamotomy).

Pain and Symptom Control: II

ROBERT P. ZANES, M.D.

The pain experience by the patient with cancer is a different kind of pain than we encounter in other illnesses and in other hospital and health care settings. This pain is not going to go away. It is usually severe and control is temporary. When the medication analgesic effect subsides, the pain remains. This is important in appreciating the need for around-the-clock regularly administered therapy.

Fifty percent of cancer patients have severe pain in the course of their illness. In our setting as in other palliative care programs, many patients are referred for pain control, a high percentage have cancer so an overwhelming majority have pain.

It is widely recognized that in the terminally ill cancer patient the sites of pain are frequently multiple. This should be identified in the admission assessment because pain in different areas may be of different types. (Figure 1.) They may be sharp or dull, aching, radiating, searing. The patient's own words may be the best terminology. The patient can also identify the intensity of the pain. At this point it is sometimes useful to obtain the opinion of an observer such as the primary care person to offer a description of that individual's identification of the pain sites and intensity as well as that in the patient's own words. Pain is a dual phenomena in the sense that it is first the perception of the physical sensation and then the emotional reaction to that sensation. As a result, there are many influencing factors, some of which will aggravate the pain and others will tend to provide relief. Figure 2 is one way of demonstrating the effect that modifying factors can have on the pain threshhold for any given individual. This figure also demonstrates the need for contribution by all members of the interdisciplinary team for pain control in a hospice setting.

Figure 1

PAIN

DUE TO TUMOR - DIRECT

- Pressure
  - Nerve
  - Hollow Organ
  - Solid Tissue Displacement
- Infiltration - Destruction
  - Bone
  - Lung
  - Brain
  - Nodal (Retroperitoneal)
  - Vascular
- Obstruction
  - Bowel
  - Biliary
  - Vascular
  - Spinal Cord
  - Respiratory
  - Renal
- Inflammation - Necrosis

PAIN

DUE TO TUMOR - INDIRECT

- Paraneoplastic Syndromes
  - Endocrinologic
  - Neurologic
  - Hematologic
  - Renal
  - Skin
  - Metabolic
- Herpes Zoster

ROBERT P. ZANES, M.D., Medical Director, The Connecticut Hospice, Inc.; Former Chief of Hematology/Oncology Section and Director, Oncology Unit, Hospital of St. Raphael, New Haven; Associate Professor of Clinical Medicine, Yale University School of Medicine.

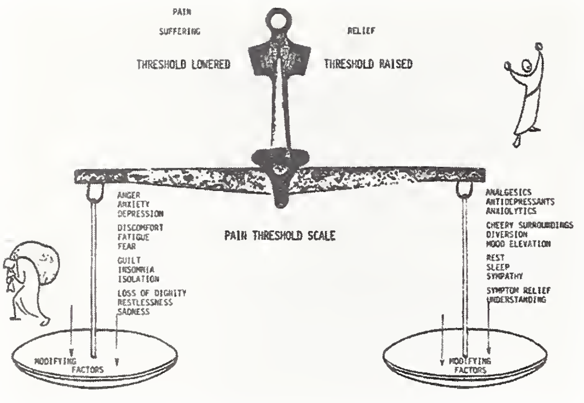

Figure 3 lists the various medications that have been used in the past four years in The Connecticut Hospice inpatient facility. The percent figures refer to all of our medication doses, whether for pain or other symptoms. Forty percent of our medications are Schedule II narcotics.

Figure 3
PAIN

Cancer Patients - 50% Have Chronic Pain
Connecticut Hospice
95% of Patients - Advanced Cancer
Because of Referral Patterns - Most have Pain

	83-84	*82-83*	*81-82*	*80-81*
Central Nervous System -	62.40%	61.80%	65.76%	60.40%
Narcotics	40.30%	39.00%	43.30%	
Major/Minor Tranquilizers	9.40%	9.40%	5.90%	
Non-Narcotic Analgesics	8.80%	9.40%	12.10%	
Anticonvulsants	3.30%	3.80%	3.20%	
Antidepressants	0.60%	0.40%	1.20%	

The utilization of escalating doses of these narcotics, flexibility in routes of administration, the addition of adjuvant non-narcotic analgesics, and breakthrough narcotic doses when necessary, are essential ingredients for good pain control.

The patient's experience in the attempt to control pain prior to admission to the hospice setting, as well as the initial assessment of the pain combine to determine which doses and which routes of administration should be used. The half-times listed are analgesic and not plasma level (Figure 4). The history from patients who were admitted from a home care setting must be evaluated carefully. Many patients and families are reluctant to use Schedule II narcotics. Physicians and nurses may be unwilling to administer the doses need for control of pain in severe cases. Compliance, therefore, must be evaluated. Some patients are admitted with excessive nausea and vomiting, preventing retention of adequate levels of medication. Every patient who is on a Schedule II narcotic is going to have problems with bowel control. This should be recognized early and some stool softeners prescribed at the same time that Morphine or other narcotics are ordered.

The patient may arrive on a continuous drip intravenous Morphine. At The Connecticut Hospice we have been extremely successful in converting these patients to another route permitting them to avoid the inconvenience and discomfort of the continuous I.V. The admitting physician must spend time with the patient and with the family to explain what the goals are and to assure them that this change in route will not be accompanied by a recurrence of the pain. The plasma half-life of Methadone and Levorphanol are considerably longer than the analgesic half-life, so that inevitably toxic levels are built up and the patient arrives with multiple toxic symptoms due to the drugs which must be identified. For this reason, as well as flexibility of routes of administration and our experience with effectiveness, these two (Levorphanol and Methadone) are used very infrequently in our setting. When a patient arrives and states that "such and such" a medication has been extremely effective, however, we will not change the drug until a more compelling reason is found. The utilization of narcotics at The Connecticut Hospice is charted in Figure 5.

Figure 4
PAIN
GUIDELINES
NARCOTIC ANALGESICS

Approximate Equinalgesic Doses

Drug	*Route*	*Dose*	*T½ (hr)*
Morphine Sulfate	PO	10-20 mg.	3-4
	IM, SC	5-15 mg.	3-4
	IV	5-8 mg.	3-4
	PR	10-20 mg.	3-4
Methadone	PO	5-15 mg.	6-8
(Dolophine)	IM, SC	5-15 mg.	4-6
Hydromorphone	PO	2-4 mg.	3-4
(Dilaudid)	PR	3-6 mg.	3-4
	IM, SC	3-4 mg.	3-4
	IV	2-3 mg.	3-4
Levophanol	PO	2-3 mg.	6-8
(LevoDromoran)	SC	2 mg.	6-8
	IV	2 mg.	4-6
Morphine Sulfate	PO	10-20 mg.	3-4
	IM, SC	5-15 mg.	3-4
	IV	5-8 mg.	3-4
	PR	10-20 mg.	3-4
Oxymorphone	PR	2-5 mg.	4
(Numorphan)	IM	1-1.5 mg.	4
Oxycodone (in Percodan)	PO	2 tablets	3-5
Codeine	PO	200 mg.	3-4
	IM/SC	120 mg.	3
Meperidine	PO	100-150 mg.	3
	IM, SC	75-100 mg.	3

The primary care nurse is permitted by the physicians' orders to exercise considerable judgment in the pain control requirements of each patient. When the initial narcotic order is written, a dosage range is permitted: 10 - 15 - 20 mgs. p.o./p.r. and flexibility and routes of administration (sub-cu 5, 7.5 - 10 mgs.). These are given every four hours, around-the-clock, not p.r.n. If pain recurs prior to the next scheduled dose, an order for breakthrough medication, usually at about half the dose level of the regular order, is provided. The physician on daily rounds will recognize that the need for breakthrough medication indicates that the base-line dosage should be increased.

Figure 5
USAGE OF NARCOTICS

	83-84	82-83	81-82	80-81
Codein	0.22%	0.60%	0.60%	1.30%
Hydromorphone	1.30%	2.00%	1.30%	5.10%
Levorphanol	3.60%	4.00%	0.80%	1.80%
Meperidine	0.00%	0.25%	1.40%	0.80%
Methadone	0.13%	0.65%	1.00%	2.70%
Morphine	84.10%	82.80%	84.80%	80.50%
Oxycodone				
with Acetaminophen	9.80%	8.10%	5.40%	5.90%
with Aspirin	0.93%	1.50%	4.50%	1.90%

For patients with bone and muscle pain, the use of non-steroidal anti-inflammatory drugs has been very effective in permitting a much lower dose level of narcotics.

The anti-convulsants, Tegratol, and less often Dilantin, are very helpful when the pain is from nerve routes or a nerve plexus. We have had the same frustrating difficulties as others in pain control for patients with post-hepatic neuralgia.

The choice for administrative routes for systemic analgesia in the hospice setting should be consistent with those of maintaining the patient's comfort as much as possible.

Our experience with the oral and rectal routes as being effective in the great majority of cases is listed on Figure 6. During the last hours or days of life the patient may be comatose or, for other reasons, unable to take anything by mouth and the subcutaneous route is used. The experience with continuous subcutaneous narcotics utilizing the pump is too limited at present to permit comparison. This is a method, however, which may offer considerable benefit for some patients, in home care as well as the inpatient program.

Figure 6
ADMINISTRATIVE ROUTES
(Comparing Systemic Routes Only)

	83-84	*82-83*	*81-82*	*80-81*
Oral	85.1%	89.3%	91.5%	92.7%
Rectal	6.8%	4.9%	2.9%	2.2%
Parenteral	8.1%	5.8%	5.6%	5.0%

Totals over 250,000 dosage units per year.

The effectiveness of the oral route in a high percentage of cases is due in large part to the hospice setting. The relaxed atmosphere, the high ratio of nurses to patients permitting much more time to encourage oral intake, the reassurance and relaxation, the opportunity to rest, all are major factors in encouraging the oral route.

The same measures listed above also play a significant role in contributing to the control of pain.

When the hospice philosophy is followed and narcotics as well as adjuvant medication for pain control are used rationally, judiciously and adequately, relief of pain may be accomplished in the great majority of cases in the terminal stages of illness, especially cancer. The present armamentarian of drugs and ancillary methods available are entirely adequate to accomplish these goals without the legalization of Heroin or other measures. Physicians and patients and families must all appreciate that high doses of narcotics, especially Morphine, in ranges over 100 mgs. every four hours may be necessary to control pain, and may be administered without excessive drowsiness and inability to communicate. Constant reassurance of the patients' and the families is necessary, but the staff is thoroughly experienced in this specialty - that pain relief can be accomplished and with it will come peripheral benefits such as ability to sleep, visit, and perhaps even enjoy a little food. These goals have been achieved in the hospice setting and are certainly possible in other health care settings when approached aggressively.

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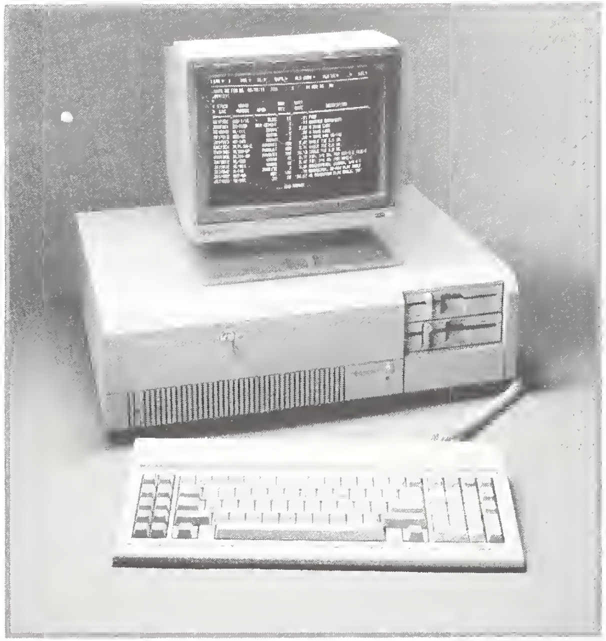

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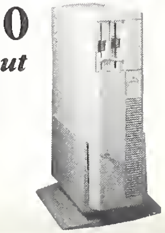

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Important Advances in Clinical Medicine

Epitomes of Progress—Orthopedics

The Scientific Board of the California Medical Association presents the following inventory of items of progress in orthopedics. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in orthopedics that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Orthopedics of the California Medical Association and the summaries were prepared under its direction.

Ischemic Necrosis of the Femoral Head

The cause of ischemic necrosis of the femoral head is unknown except in displaced fractures of the femoral neck, Gaucher's disease and decompression sickness (air embolism). This disorder occurs frequently in patients with alcoholism and those who have had large doses of corticosteroids. The cause is controversial although there is some evidence that alcohol and steroids produce fat cell and fat metabolism aberrations that affect and encroach on the intramedullary vascular system, thus producing an avascular area in the femoral head. In many cases the necrosis is idiopathic.

Diagnosis depends on taking a careful history and the results of a physical examination and x-ray evaluation. Supportive evidence may be supplied by radioisotopic scanning and laminography. Frequently radiographic findings are inconclusive so that diagnosis will depend on the results of a careful dynamic pressure study and core biopsy.

Treatment is based on the six-stage classification of Marcus and others. Stages V and VI are essentially the same and can be combined. In stages I and II, core biopsy with decompression or bone grafting techniques are effective in more than 85% of cases. These surgical procedures are not satisfactory in later stages, during which replacement arthroplasty, osteotomy and osteochondral allografts are more viable options. Electrical stimulation has been advocated recently as a promising technique for treatment; however, the evidence to support this suggestion is at best weak.

Until the cause of femoral head osteonecrosis has been clarified and preventive treatment devised, a surgical procedure is the best available treatment. Early recognition and surgical treatment during stages I and II offer the best hope for salvaging a diseased femoral head. Osteotomy and allograft techniques may prove successful during the advanced stages (III and IV), but failure of these procedures will necessitate a replacement operation, which is less than ideal.

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Myocutaneous Flap for Soft Tissue Reconstruction

The myocutaneous flap has become a versatile and safe procedure for soft tissue reconstruction. If done properly, it provides skin and soft tissue coverage with tissue that has a rich blood supply, a large and long vascular

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pedicle and highly predictable anatomy. The technique is especially useful in covering the large areas of skin and soft tissue lost following trauma, infection, tumor resection or in scarred or irradiated recipient beds. In addition to wound coverage, myocutaneous flaps are useful to restore form, contour and function.

Myocutaneous flaps have been used in a number of ways. (1) A flap can be raised, leaving its vascular pedicle attached. The flap can then be rotated to cover an adjacent defect without interruption of its blood supply. An example of this is a latissimus dorsi myocutaneous flap rotated to cover a posterior midline exposed Harrington rod. (2) The muscle alone can be transferred with its blood supply if the addition of the overlying skin and fat will make the flap too bulky. In this case a split-thickness skin graft is placed over the muscle belly. (3) With the development of microvascular techniques it is possible to transfer a free vascularized muscle or myocutaneous flap to a distant wound in one stage. An example of this is using a free vascularized latissimus dorsi flap to cover an open femur or tibia fracture that has an extensive soft tissue defect. Besides providing coverage, free gracilis muscle or myocutaneous flaps have been used successfully to provide active finger flexion or extension in Volkmann's ischemic contracture by suture of the nerve supply of the gracilis to the appropriate motor nerve of the recipient site.

A clinician needs detailed knowledge of the vascular anatomy and patterns of blood supply to the muscles and their limitations to treat wounds by a myocutaneous flap procedure.

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Complications of Chemonucleolysis

Chymopapain was approved for clinical use in the United States for the treatment of herniated lumbar discs on November 10, 1982. Currently, two products are available: Chymodiactin (Smith) and Discase (Baxter-Travenol).

Experience of more than 80,000 injections has proved chymopapain to successfully relieve radicular pain in 75% of cases (range 62% to 90%). Minor problems with chemonucleolysis include a failure rate of approximately 25% and transient worsening of back and leg pain after the injection. Major complications include potentially fatal anaphylaxis, neurologic risk and septic discitis.

Allergic complications of chemonucleolysis range from pruritus or urticaria to fatal anaphylaxis. The overall incidence of anaphylaxis is 0.5%, with 0.3% in men and 0.9% in women. When the enzyme is given with local anesthesia the overall incidence of anaphylactic reactions is 0.4%—0.2% in men and 0.7% in women. With general anesthesia, the overall incidence is 0.6%, with 0.4% of men and 1.0% of women given the chemonucleolytic agent experiencing anaphylaxis. The onset of 96% of anaphylactic reactions is within 20 minutes of injection. Of those patients who have had a reaction to a test dose alone (theoretically the most sensitive group), 94% experienced reactions within ten minutes. There have been no deaths caused by anaphylaxis in patients under local anesthesia. The role of serologic determinations of IgE antibody to chymopapain and skin-testing methods is currently under investigation. False-negative results of serologic testing have occurred, and thus vigilance remains essential.

To lessen the risk of anaphylaxis, physicians should observe certain precautions. Patients with a known sensitivity to chymopapain, papaya or its derivatives or to a previous chymopapain injection should not be given the drug. An intradiscal test dose of 0.2 ml of chymopapain followed by a 10- to 15-minute observation period is recommended. Patients who have concurrent medical conditions that include cerebrovascular and cardiovascular disease, which could compromise successful resuscitation, should not be given chymopapain. Pretreatment with histamine (H_1 and H_2) antagonists including diphenhydramine hydrochloride and cimetidine is recommended. Prompt recognition and aggressive treatment of suspected anaphylaxis with epinephrine and intravenous administration of fluids is essential.

Neurologic reactions including cerebral hemorrhage, sudden onset of paraparesis or paraplegia, transverse myelitis and other neurologic complications have been reported. Because technical factors including subarachnoid injection of radiographic contrast or chymopapain, or both, have been implicated, avoidance of discographic procedures and meticulous technique are essential.

Transverse myelitis has been reported after chemonucleolysis at an incidence of 1 per 18,000. The spontaneous incidence of transverse myelitis has been reported as approximately 1 per 100,000 person-years. These patients have a delayed onset of paraparesis or paraplegia—about two or three weeks postinjection—without prior signs or symptoms. Some researchers suggest that delayed hypersensitivity of immune complex disease is caused by chymopapain or antigenic breakdown products of the nucleus pulposus but these theories remain unproved.

Discitis, both aspectic and septic, has been reported. Septic discitis is usually staphylococcal; meningitis and death complicating septic discitis have been reported, so meticulous attention to sterile technique is essential.

Although successful in 75% of cases, chemonucleolysis is associated with remote but significant risks. Proper patient selection, meticulous technique, prompt recognition and treatment of complications and thorough informed consent are essential.

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Electrical Stimulation of Ununited Fractures

Electrical stimulation of ununited fractures is now an accepted technique available to all orthopedic surgeons. Some of the causes of delay or nonunion of fractures are apparent, including infected fractures, fractures with a significant gap and severe open fractures with major soft tissue loss. Nonunions can occur, however, in young, healthy persons who sustain a closed fracture with minimal displacement.

Grafting the unhealed site with bone from the iliac crest has been the conventional method to promote healing. Rigid fixation using internal or external metal devices also has a high rate of success, but these procedures carry a risk of infection and may be unsuccessful even after several attempts. Electrical stimulation is an alternative that is effective and the newer forms have few risks.

The following three techniques of electrical stimulation are available: (1) totally invasive: the electrode is embedded in the fracture site during an open surgical procedure; (2) semi-invasive: under local anesthesia in the operating room, small stainless steel wire electrodes are placed percutaneously into the fracture site, and (3) noninvasive: the technique of inductive coupling using large electromagnetic coils to induce an electrical field at the nonunion site.

There are disadvantages to these techniques: healing may take up to six months in large bones and patients may not bear weight for at least the first three months of treatment. All procedures but the noninvasive coil electrodes have a risk of infection.

A new type of noninvasive electrical stimulation using capacitive coupling is in its final stages of patient testing. In capacitive coupling, an electrical field is induced in bone by small stainless steel electrodes placed on a patient's skin at the nonunion site. The device is powered by a 9-V battery attached to the outside of the cast allowing the patient to move about freely. This is an office procedure, and the patient may bear weight as tolerated during the course of treatment.

These electrical stimulation techniques are reported to be successful in 70% to 80% of cases, but the rate varies with the location of the nonunion. Nonunion of the tibia responds to electrical stimulation—more than 90% of patients heal completely, whereas nonunion of the humerus responds very poorly. Humeral nonunions frequently develop a synovial pseudarthrosis (false joint) consisting of a fluid-filled sac between the fracture fragments. This allows gross motion at the nonunion site and should be treated by surgical removal of the synovial sac, rigid fixation and bone grafting. If this treatment fails, electrical stimulation may be successful once the nonunion has been well stabilized.

At the present time there is no clear evidence that electrical stimulation is effective in treating fresh fractures, nor that adding this treatment to conventional bone grafting will significantly increase the chance of healing.

Bone grafting and rigid fixation by either external or internal devices are still acceptable techniques and have an equal or slightly higher success rate when compared with electrical stimulation. However, all require a surgical procedure with the accompanying risk of infection.

Electrical stimulation is a safe and effective addition to the procedures available to orthopedic surgeons for the treatment of unhealed fractures.

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Management of Major Pelvic Ring Fractures

Fractures of the pelvis can be divided into minor and major ones. The minor fractures include avulsions and those that ostensibly only disrupt the pelvic ring at one point. Major fractures involve the pelvic ring at two or more diametric positions and may be stable or unstable. Most fractures caused by shearing forces, some caused by anteroposterior compression and occasionally those caused by lateral compression are unstable.

Instability is suggested by a patient's history, physical examination and by the results of special radiologic examinations. Anteroposterior and 45-degree inlet and outlet radiographs of the pelvis are essential. Cephalad migration of one hemipelvis, fracture of the fifth lumbar transverse process and avulsion fractures of the ischium and ischial spine all suggest instability. The possible points of pelvic ring disruption include the sacrum, sacroiliac joint, ilium, acetabulum, pubic arches and symphysis pubis. Computed tomography is often helpful in confirming the clinical and plane radiographic impression and assists in planning therapy.

The time-honored treatment of pelvic fractures with slings and traction is now rarely indicated and may in fact be detrimental in unstable fractures caused by lateral compressive forces. The pelvic sling is usually uncomfortable, makes nursing difficult, prolongs hospital stay and often will not achieve a good reduction or stabilization.

Recent advances in external and internal fixation techniques have greatly improved the capability to deal with the unstable pelvic fracture. A simple tie-beam arrangement with two Schanz type pins in each anterior iliac crest region connected by rods stabilizes anterior disruptions when the posterior sacroiliac interosseous ligaments are intact. More massive external fixators with pins above and below the anterior superior iliac spine may be used for the Malgaigne type fracture. However, the emphasis has recently been placed more on internal fixation with screws, rods or plates posteriorly combined with double plating of the symphysis pubis or a simpler frame anteriorly.

The advantages of external fixators and internal fixation techniques include better stabilization, improved control of pain and bleeding, easier nursing and shorter hospital stay.

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External Fixation of Tibia Fractures

Management of a severe open tibia fracture with extensive soft tissue injury continues to pose a therapeutic dilemma for most orthopedic surgeons. Although external fixation has been practiced for centuries, the renewed interest in this treatment has led many orthopedists to review and modify their fracture management protocols. The classic “pins and plaster” technique is a modification of the external fixation system. The lack of accessibility to the wound, unstable pin fixation, inability to reset the fracture if necessary and bulky casts have led trauma surgeons to search for a more rigid, low profile, external fixation system.

Although there are many variations on a theme, external fixation frames are basically designed for one-plane or two-plane fixation, depending on the stability of the fracture. Less rigid frames consisting of one-plane or half-pin anterolateral frames are indicated in the open type II or III tibia fracture with minimal comminution and minimal soft tissue involvement. On the other hand, two-plane frame fixation, as shown by the quadrilateral or the Delta frame, is indicated for severe open fractures of the tibia where there is segmental bone loss, severe comminution or massive soft tissue injury. The key difference is that one-plane frame fixation provides less stability than the two-plane or Delta frame fixation configuration.

Tibia external fixation is technically facilitated by the use of C-arm fluoroscopy and a radiolucent table extender. This technique preserves precious intraoperative time that is otherwise lost awaiting development of the roentgenograms. Occasionally stability is enhanced by one or two strategically placed intrafragmentary compression screws that provide temporary rotational control, length and reduction while the external frame is being constructed. After the operation, dorsiflexion foot splints should be applied to prevent equinus deformities. Fastidious care of the pin should be instituted and the leg should be elevated to prevent edema during the early phases of treating the wound.

Prolonged immobilization of patients has been implicated in nonunions of the tibia treated with external fixation. A recent review of tibia fractures treated at the University of California, Davis, Medical Center in Sacramento suggests that a brief period of external fixation—six to eight weeks—followed by early bone grafting and the use of weight-bearing casts has resulted in high rates of union and few pin tract complications. This temporal relationship provides maximum soft tissue benefit and does not jeopardize bone union.

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Vidal J, Buscayret C, Connes H, et al: Guidelines for treatment of open fractures and infected pseudarthroses by external fixation. Clin Orthop 180:83-95, Nov 1983.

Management of Long Bone Fractures With External Fixators

In recent years external fixation has become the treatment of choice in the management of type III fractures of long bones. The advantages of rigid external fixation in these injuries is that it allows for complete visualization of the soft tissues, ease of inspection and accessibility and allows for repeated debridements without removal of cumbersome dressing and plaster casts.

In addition to the tibia, we have found external fixation useful in the management of fractures of the femur that involve considerable soft tissue and bony injury, when intermedullary fixation is not appropriate or not possible. External fixation allows the patient to return easily to the operating room for wound debridement and delays primary closure or skin-grafting or both until the appropriate time.

External fixation can be used in type III injuries of the humerus and forearm when there is extreme soft tissue destruction and bony loss. Many of these injuries are associated with close-range bullet wounds, which cause extensive comminution of the long bones. External fixation allows us to maintain bony alignment and length and adequately debride soft tissue areas preparatory to reconstruction of both the bony and soft tissue envelopes. Our goals in these injuries include closure of the wounds with appropriate rotational flaps or grafts or both within the first eight days.

With external fixation in place and frames designed to manage the type of stability needed, we can maintain bony alignment and soft tissue length until wounds are well healed and decide later if we wish to return to the injured area for definitive bone-grafting. Many of these patients have more than one injury and external fixation allows the patient to get out of bed soon, which can improve pulmonary and cardiovascular management and decrease complications in these areas.

If microvascular techniques or local coverage is not possible, external fixation can maintain leg position in cross-leg pedicle flaps—a good alternative to using large plaster casts. Patients are more comfortable and the complete flap can be seen because there are no casts or occlusive dressings in the way.

External fixation is of benefit in extremely unstable comminuted closed fractures and rigidity of the frames can be modified to allow for alignment, but also allow for transmission of forces across the fracture site to stimulate callus formation. Unfortunately, the exact degree of rigidity for ideal periosteal new bone formation is not known and awaits further research.

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Health Implications of Obesity

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Introduction

Current knowledge of human obesity has progressed beyond the simple generalizations of the past. Formerly, obesity was considered fully explained by the single adverse behavior of inappropriate eating in the setting of attractive foods. The study of animal models of obesity, biochemical alterations in man and experimental animals, and the complex interactions of psychosocial and cultural factors that create susceptibility to human obesity indicate that this disease in man is complex and deeply rooted in biologic systems. Thus, it is almost certain that obesity has multiple causes and that there are different types of obesity.

To assess the health implications of obesity, new knowledge and new epidemiologic observations have introduced a variety of complications that must be addressed. Thus, a reassessment of definitions and measurements of obesity is required. There is controversy surrounding the interpretation of data showing an association of body weight with morbidity and mortality. The interpretations of data from different studies have been complicated by the confounding effects of smoking behavior, the coexistence of diseases other than obesity, and variations in methods of data collection and followup. Because population samples in some studies have not been representative of the U.S. population, there have been uncertainties as to how far their conclusions can be generalized for recommendations for dietary advice and treatment.

There is evidence that an increasing number of children and adolescents are overweight. Even though all overweight children will not necessarily become overweight adults, the increasing prevalence of obesity in childhood is likely to be reflected in increasing obesity in adult years. The high prevalence of obesity in our adult population and the likelihood that the nation of the future will be even more obese demand a reassessment of the health implications of this condition.

For the special purpose of resolving the pressing questions relating to the health implications of obesity, the NIH Office of Medical Applications of Research, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, and the National Heart, Lung, and Blood Institute convened a consensus development conference on the health implications of obesity on February 11-13, 1985. After listening to 1½ days of presentations by experts in the field, hearing audience comments, and reviewing the medical literature, a consensus panel representing the professional fields of nutrition, nutritional biochemistry and metabolism, endocrinology, internal medicine, gastroenterology, epidemiology, biostatistics, psychiatry, pediatrics, and family medicine considered the evidence and agreed on answers to the following questions:

- What is obesity?
- What is the evidence that obesity has adverse effects on health?
- What is the evidence that obesity affects longevity?
- What are the appropriate uses and limitations of existing height-weight tables?
- For what medical conditions can weight reduction be recommended?
- What should be the directions of future research in this area?

Only the above questions were addressed. Extremely important issues relating to obesity such as prevention, treatment (including exercise), and the impact on society were not addressed by this panel. The special relationship of obesity to lower socioeconomic status was not addressed.

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1. What is Obesity?

Adipose tissue is a normal constituent of the human body that serves the important function of storing energy as fat for mobilization in response to metabolic demands. Obesity is an excess of body fat frequently resulting in a significant impairment of health. The excess fat accumulation is associated with increased fat cell size; in individuals with extreme obesity, fat cell numbers are also increased. Although the etiologic mechanisms underlying obesity require further clarification, the net effect of such mechanisms leads to an imbalance between energy intake and expenditure. Both genetic and environmental factors are likely to be involved in the pathogenesis of obesity. These include excess caloric intake, decreased physical activity, and metabolic and endocrine abnormalities. Hence, a number of subtypes of obesity exist.

The precise determination of the amount of body fat requires technically sophisticated methods that are available only in research laboratories. For public health studies and clinical practice, simple and convenient anthropometric measurements based on height, weight, and skinfold thickness are recommended. For adults of 20 years and older, two methods are now in wide use: (1) estimation of relative weight (RW = measured body weight divided by midpoint of medium frame desirable weight recommended in the 1959 or 1983 Metropolitan Life Insurance Company tables) and (2) calculation of body mass index (BMI = [body weight in kg] divided by [height in m]^2). Because body composition varies among individuals of the same height and weight, these measurements only approximate the precise magnitude of fatness. Nevertheless, they correlate with the risk of adverse effects on health and longevity. Separate criteria must be used for evaluating fatness in children and adolescents.

Adipose tissue depots do not constitute a uniform organ; fat cells around the waist and flank and in the abdomen are more active metabolically than those in the thigh and buttocks. The location of body fat has emerged as an important predictor of the health hazards of obesity. Sites of body fat predominance are easily measured by the ratio of waist to hip circumferences. High ratios are associated with higher risks for death and illness.

Based on indices of body fat, studies of large populations have shown that there is a continuous relationship between RW or BMI and morbidity and mortality. Thus, it becomes important to establish ranges of these indices as guidelines for developing appropriate and effective approaches for the treatment and prevention of obesity.

Since the amount of body fat, as estimated by the above indices, is a continuous variable within the population, all quantitative definitions of obesity must be arbitrary. The panelists agree that an increase in body weight of 20 percent or more above desirable body weight constitutes an established health hazard. Significant health risks at lower levels of obesity can present hazards, especially in the presence of diabetes, hypertension, heart disease, or their associated risk factors.

2. What is the Evidence That Obesity has Adverse Effects on Health?

Clinical observations have long suggested a connection of obesity (particularly in its extreme forms) with a variety of illnesses. Obesity creates an enormous psychological burden. In fact, in terms of suffering, this burden may be the greatest adverse effect of obesity. At the present time, the strongest evidence that obesity has an adverse effect on physical health comes from population-based prevalence (cross-sectional) and cohort (followup) studies. These data are complemented by weight-reduction trials.

The most comprehensive data on prevalence of cardiovascular disease (CVD) risk factors and obesity are the National Health and Nutrition Examination Surveys (NHANES). NHANES I was conducted from 1971 through 1974 and NHANES II from 1976 through 1980. Both were based on a representative sample of residents of the United States.

Data from NHANES II were analyzed by comparing several parameters for the subjects at or above, or below, the 85th percentile of the reference population.* At or above this cutoff point, males have a BMI ≥ 27.8 and females have a BMI ≥ 27.3. This analysis showed a strong association between the prevalence of obesity and CVD risk factors. Based on these criteria, the prevalence of *hypertension* (blood pressure greater than 160/95) is 2.9 times higher for the overweight than for the nonoverweight. The prevalence is 5.6 times higher for the young (20 through 44 years old) overweight than for the nonoverweight subjects in this age group. The prevalence is twice as high for the obese older (45 through 74 years old) group as it is for the nonoverweight subjects of the same age. The prevalence of *hypercholesterolemia* (blood cholesterol over 250 mg/dl) in the young overweight age group is 2.1 times that of the nonoverweight group; overweight and nonoverweight subjects show similar prevalences for hypercholesterolemia after age 45.

Levels of blood pressure and serum cholesterol vary with levels of obesity in a continuous manner. This relationship holds for the so-called normal as well as the elevated range in observational studies. Intervention studies confirm that levels of blood pressure and serum cholesterol can be reduced by weight reduction.

The prevalence of reported *diabetes* is 2.9 times higher in overweight than nonoverweight persons in the NHANES data. Type II diabetes (maturity onset or noninsulin-dependent mellitus—NIDDM) appears to be an inherited disease; however, studies clearly show that weight reduction can reverse the abnormal biochemical characteristics of NIDDM.

Coronary Artery Heart Disease (CAHD)

The relationship of obesity to the incidence of CAHD has been studied in a large number of cohort studies. In contrast to the consistent relationship of obesity to CAHD risk factors found in the overwhelming majority of prevalence studies, widely divergent results have been reported for the relationship of obesity to the incidence of CAHD. Thus, the eight cohort studies of the U.S. Pooling Project found discrepant results, including no association, a U-shaped relationship, and a positive relationship of obesity to CAHD. However, when data from these same studies were combined, there was a positive relationship of obesity to the risk of CAHD. Possible explanations for the discrepant findings include differences in health status of industrial workers in contrast with health status of the total population, varying duration of followup among the studies, and inadequate sample sizes.

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*Noninstitutionalized, nonpregnant U.S. residents, ages 20 to 29, 1976-1980.

Studies in which obesity predicted CAHD usually found that obesity was not a risk factor independent of the standard risk factors. However, the Framingham Study, a large general population-based study that is strengthened by having long duration followup data, recently disclosed an increasing risk of CAHD with increasing levels of obesity, independent of the other standard risk factors.

Other recent studies indicate that the distribution of fat deposits may be a better predictor of CAHD than is the degree of obesity. Excess abdominal fat is more often related to disease than are fat deposits in the thigh or gluteal areas.

Cancer

There are numerous epidemiological studies of obesity and site-specific malignancies, one of the largest of which is the American Cancer Society (ACS) Study involving more than 1 million men and women. Through the last followup year (1972), 93 percent of the subjects were traced (alive or dead). Obese males, regardless of smoking habits, had a higher mortality from cancer of the colon, rectum, and prostate. Obese females had a higher mortality from cancer of the gallbladder, biliary passages, breast (postmenopausal), uterus (including both cervix and endometrium, and ovaries. In the case of endometrial cancer, women with marked obesity showed the highest relative risk (5.4) for the obese versus the nonobese.

3. What is the Evidence That Obesity Affects Longevity?

Obesity, when measured by relative weight (actual weight as a percentage of average or desirable weight for a given height/age/sex group) has an adverse effect on longevity. Convincing evidence of this has been evaluated in four very large insurance studies (1903 to 1979), the Framingham 30-Year Followup Study, the American Cancer Society Study, and other smaller cohort studies. Some additional cohort studies do not show this adverse effect, but these studies present problems in interpretation due to small size, followup 10 years or less, occupational bias, or a population otherwise not representative of the U.S. population. The greater the degree of overweight, the higher the mortality ratio or excess death rate. Both mortality ratio and excess deaths per 1,000 per year increase with length of followup. Two small groups of insurance policyholders who reduced weight to acceptable levels for standard insurance had a decline in mortality to normal. In the insurance studies, the increased mortality with overweight was observed in normotensive men and women, without other major impairment, who would have been eligible for standard insurance rates except for being overweight. Smokers were not differentiated from nonsmokers. In the Framingham and ACS studies, the increase in excess mortality with increasing degrees of overweight was present in both smokers and nonsmokers.

The pattern of excess mortality variation with relative weight is illustrated in men ages 15 to 39 years at entry from data in the 1979 Build Study:

Weight Relative to Average Weight	*Mortality Ratio*
65-75%	105%
75-95	93
95-105 (average)	95
105-115	110
115-125	127
125-135	134
135-145	141
145-155	211
155-165	227

For those with relative weight of 125 to 135 percent at entry, the aggregate mortality ratio was 134 percent, as shown above. When mortality was analyzed by duration, the mortality ratio increased from 110 percent at the 0 to 5-year interval to 169 percent at the 15 to 22-year interval. The weight class for lowest mortality shown above is below the average weight category. There is higher mortality in the lowest relative weight class, 65 to 75 percent of average. In extreme obesity ("morbid" obesity), the mortality ratio has been reported in a small series as being of the order of 1,200 percent. A recent analysis has shown that the body mass index of minimum mortality, derived from the data in the 1979 Build Study, increases with age in a straight line relationship, the lines for male and female being virtually identical. The 1959 and 1983 Metropolitan Life Insurance Company tables of ranges of weight with minimal mortality do not provide for any age variation.

The increase in mortality versus relative weight is steeper in men and women under age 50 than in older persons, and the increase with duration is also steeper. These findings suggest that particular attention should be paid to efforts to reduce weight in younger patients. Recent studies suggest that the distribution of fat deposits may be a better predictor of mortality than BMI or RW. If confirmed, it may be important in the future to measure fat distribution in addition to using height-weight tables.

4. What are the Appropriate Uses and Limitations of Existing Height-Weight Tables?

There is consensus that a measure of obesity is needed to overcome the subjectivity introduced by simply relying on visual inspection as an estimate of obesity. Equipment for measuring height and weight, height-weight tables, and weight-related indices are widely available.

Various indices for adults are available. These can be categorized into three groups:

- Tables of average weights by height and age.
- Tables of desirable weights for height associated with lowest mortalities in insured populations.
- Indices that are derived from height and weight such as body mass index.

Extensive height-weight data (e.g., National Center for Health Statistics) are available for estimating obesity in infants and children.

Tables of Average Weights by Height and Age

These tables report cross-sectional data on a representative sample of the noninstitutionalized population living in the United States. They represent averages rather than optimal data and may be useful for descriptive purposes.

Tables of Desirable Weights by Height

These tables are based on weights associated with the lowest mortality rate among insured populations of adults. At least two versions are in current use: the 1959 Metropolitan Life Insurance Company table and the 1983 revision.

Confusion exists as a result of the slight increases in desirable weights seen in the 1983 as opposed to the 1959 tables. In the 1983 tables, desirable weights for men and women in the shortest stature groups are 12 and 14 pounds higher respectively than they were in 1959. It is recognized that such increased body weight may contribute to high blood pressure, hypercholesterolemia, and glucose intolerance or similar risk factors, apart from the impact of weight on mortality. Neither the 1959 nor the 1983 height-weight tables reflect current weight and mortality relationship for the American population, since, of necessity, the deaths reflect the mortality experiences of policyholders with a cutoff date of 11 years prior to the publication of the tables.

Uses

- Clinical: To establish the presence of obesity and the approximate degree of risk and to guide treatment.
- Educational and informational.
- Research.

Limitations

- Tables are formulated on specific populations; they may not be applicable to the entire population, particularly those of lower socioeconomic and some ethnic groups.
- The mortality and morbidity related risks of obesity are influenced by concurrent risk factors such as smoking.
- Tables do not provide information on body fat distribution or degree of obesity.
- Frame size as used for estimation of lean (fat-free) body mass is subjectively determined in the 1959 tables. The use of elbow width to judge frame size, as suggested in the 1983 tables, may or may not eliminate the problem.
- Age is not taken into account.

Body Mass Index

The body mass index

$$\text{BMI} = \frac{\text{Body wt in kg}}{(\text{Ht in m})^2}$$

is a simple measurement highly correlated with other estimates of fatness. It minimizes the effect of height and is useful for descriptive or evaluative purposes. It has the advantage of permitting comparison of populations. The major limitation of the BMI is that it is difficult to interpret this mathematical index to patients and to relate it to weight that must be lost.

The consensus panel recommends that physicians adopt this measure as an additional factor in evaluating patients and that nomograms be used to facilitate calculations of BMI.

5. For What Medical Conditions Can Weight Reduction be Recommended?

Weight reduction may be lifesaving for patients with extreme obesity, arbitrarily defined as weight twice the desirable weight or 45 kg (100 pounds) over desirable weight. When obesity is accompanied by severe cardiopulmonary manifestations, as in the Pickwickian syndrome, weight reduction should be part of the treatment for this medical emergency.

In view of the excess mortality and morbidity associated with obesity (as discussed above), weight reduction should be recommended to persons with excess body weight of 20 percent or more above desirable weights in the Metropolitan Life Insurance Company tables (using the midpoint of the range for a medium-build person). In the 1983 tables, 20 percent over desirable weight is a higher weight than would be obtained by the use of the 1959 tables. The maximum increase is found in those of short stature and does not exceed 17 percent for men or 13 percent for women. Although not a specific recommendation of the panel, use of the lower weights as goals would be advisable in the presence of any of the complications or risk factors summarized below. The body mass index values, which correspond to 20 percent above desirable weight, are 27.2 and 26.9 for men and women, respectively, using the 1983 tables and 26.4 and 25.8 for men and women, respectively, using the 1959 tables. These values are not substantially different from the BMI values for men and women identified with the lower cutoff point for overweight as determined by the National Center for

Health Statistics—27.8 and 27.3 for men and women, respectively (NHANES II population, bare feet, no clothes).

Weight reduction is also highly desirable, even in patients with lesser degrees of obesity, in many other circumstances, including the following:

- Noninsulin-dependent diabetes mellitus, a family history of diabetes mellitus, women with a history of gestational diabetes or history of birth of an infant large for gestational age.
- Hypertension (hypertension due to specific, identifiable causes such as renal artery stenosis or pheochromocytoma should be treated for those specific causes).
- Hypertriglyceridemia or hypercholesterolemia.

Weight reduction is likely to be helpful, although the benefits may not be as clear as in the circumstances listed above, in other circumstances, including:

- Coronary artery heart disease.
- Gout.

In any circumstance in which excessive weight imposes functional burdens, weight reduction may improve functioning of the affected system, organ, or region. Such conditions include many common disorders, for example:

- Heart disease of other types.
- Chronic obstructive pulmonary disease.
- Osteoarthritis of the spine, hips, or knees.

Weight reduction in the treatment of these conditions should be under the direction of a physician because accurate diagnosis is needed before treatment is started, and weight reduction may have to be accompanied by other treatments. In addition to physicians, the assistance of other health professionals is critical for treatment in any weight-reduction program. When exercise is prescribed as an adjunct to other methods of weight-reduction, assessment by a physician of the cardiopulmonary risk of exercise is especially important.

The panel views with concern the increasing frequency of obesity in children and adolescents. Obese children should be encouraged to bring their weight to within normal limits. Although childhood obesity does not necessarily lead to obesity in adulthood, there is evidence that it is a significant risk factor for adult obesity. Because dietary restriction can adversely affect parent-child relationships, eating behavior, and growth and maturation, physicians must carefully monitor any dietary restrictions.

6. What Should be the Directions of Future Research in This Area?

It is vitally important to increase the understanding of obesity to enable prevention. Because obesity is so prevalent, any effective strategy for prevention will have public health importance. The following areas of investigation, dealing mainly with the questions addressed to this panel, are stressed:

- In infancy and childhood, we must search for biological (genetic, metabolic, or anthropometric) markers as predictors of adult obesity. Having such predictors would permit the study of the development of the disease, would provide a powerful epidemiological tool, and would allow treatment to begin very early in life.
- The factors that regulate the regional distribution of fat and methods to assess the distribution must be developed. We need to define the mechanism by which body fat distribution is associated with adverse effects of obesity.
- Regulation of energy balance is complex, but many aspects have begun to yield to investigation. Promising leads are:
  - effects of the central and autonomic nervous systems and the endocrine system.
  - adipose tissue cellularity (in tissue culture) and metabolism.
  - the role of various components of thermogenesis in the overall control of energy balance.
  - control of food intake (e.g., endogenous opioids).
  - satiety factors (e.g., gut hormones).
- Studies utilizing cultural and physical measurements in several cultures, including minority, low socioeconomic, and rapidly changing cultures, should be conducted.
- The data from large CAHD cohort studies initiated 20 to 30 years ago should be identified and archived. Archiving should be encouraged for data obtained from ongoing and future studies.
- Relative risk tables that incorporate both fat distribution and height-weight data should be developed.

Great advances of modern biological science as applied to obesity can generate new information that can now be tested at the bedside. Clinical investigation utilizing the biological advances is timely. The best of public health sciences, including the anthropological and sociological, should be brought into the study of the prevention of obesity.

Conclusions

The evidence is now overwhelming that obesity, defined as excessive storage of energy in the form of fat, has adverse effects on health and longevity. Obesity is clearly associated with hypertension, hypercholesterolemia, NIDDM, and excess of certain cancers and other medical problems. Height and weight tables based on mortality data or the body mass index are helpful measures to determine the presence of obesity and the need for treatment. Thirty-four million adult Americans have a body mass index greater than 27.8 (men) or 27.3 (women). At this level of obesity, which is very close to a weight increase of 20 percent above desirable, treatment is strongly advised. When diabetes, hypertension, or a family history for these diseases is present, treatment will lead to benefits even when lesser degrees of obesity are present.

Obesity research efforts should be directed toward elucidation of biologic markers, factors regulating the regional distribution of fat, studies of energy regulation, and studies utilizing the techniques of anthropology, psychiatry, and the social sciences.

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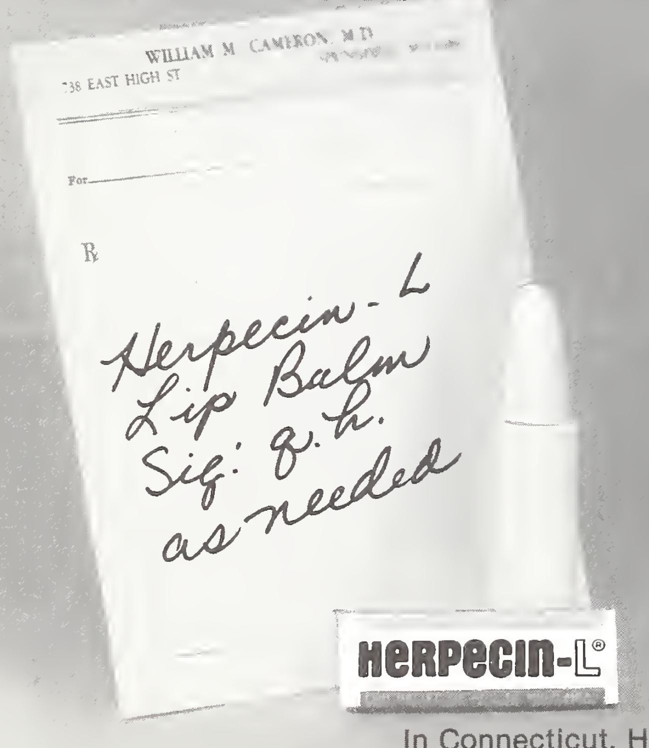

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Why Britain Can't Afford Informed Consent

ROBERT SCHWARTZ AND ANDREW GRUBB

In the case of Mrs. Amy Sidaway, the House of Lords has rejected the "American" legal doctrine of informed consent, which is based on patients' rights, in favor of a standard based on the obligations of the reasonable physician. The British National Health Service, with centralized planning, prospective funding, and limited resources, is unlikely to provide a safe harbor for a doctrine based on individual choice in health care.

Despite partial paralysis, Mrs. Amy Sidaway attended the first day of the House of Lords' three-day hearing in her malpractice case, *Sidaway* vs. *The Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital,* last December.[1] An unusually perservering person, she is a comparative rarity as a malpractice plaintiff in England. Fewer than 1,000 medical malpractice actions were filed in 1981, the last year for which figures are available.[2] In February 1985 the House of Lords, as expected, affirmed lower court decisions denying her claim.

More than ten years after active legal discussion of informed consent began in the U.S., the first case based firmly in that doctrine came to England's highest court only to reject the importation of the "American" doctrine.

Mrs. Sidaway had been suffering back pains since she injured her elbow in 1958. In 1960 a respected neurosurgeon, Mr. Falconer, performed spinal surgery that for a time, eased her pain. Mr. Falconer examined Mrs. Sidaway each year for the next decade, and in late 1973 he wrote to her, inquiring about her condition. As one appellate judge later noted, "Bearing in mind that the plaintiff was not a private patient, it is a great tribute to Mr. Falconer's compassion and interest that he wrote as he did."

When Mrs. Sidaway responded that much of the pain had returned, Mr. Falconer recommended readmission to the hospital for further testing. She remained on the National Health Service waiting list for several months, and her readmission was further delayed by a hospital strike. In late 1974 the tests were performed, and Mr. Falconer determined that she needed a laminectomy—an operation to remove a thin plate from a vertebra. Mrs. Sidaway described Mr. Falconer as a man of "very, very few words," and the trial court judge found him to be "an obsessively meticulous surgeon. . .and a reserved, slightly autocratic man of 'the old school'."

The judge determined that before seeking her consent to the laminectomy Mr. Falconer had informed Mrs. Sidaway of the possibility of disturbing a nerve root, but not the 1 to 2 percent chance of spinal cord damage, the consequences of which could range from the mild to the catastrophic. Mrs. Sidaway agreed to the operation. During the course of the surgery, she was seriously injured and remains partially paralyzed. As a result, she was forced to give up her employment as a file clerk and her leisure activities, which included sewing and gardening.

It is virtually impossible for middle-class plaintiffs to afford malpractice actions in England. The vast majority are brought by clients like Mrs. Sidaway who qualify on financial grounds for legal assistance. Some time after the laminectomy Mrs. Sidaway found a solicitor willing to commence a malpractice action against the estate of Mr. Falconer, who had since died, and the hospital where the surgery was performed.

She did not question the quality of Mr. Falconer's surgery, which, everyone agreed, had not been negligent. Her entire claim was based upon his failure to inform her of the risks of injury inherent in the surgery. The trial court judge concluded, first, that the risk that Mr. Falconer had failed to communicate was a "material" one, and, second, that it was the practice of some responsible physicians not to inform their laminectomy patients of this material risk before seeking their consent. Neither of these findings has ever been challenged.

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To decide the case, the judge had to determine which legal standard was to be applied to evaluate the information that a physician must provide to a patient before carrying out a medical procedure. The plaintiff argued that the physician has an obligation to obtain informed consent independent of the duty to treat and care for his patient in a reasonable manner. Thus, the plaintiff urged the court to adopt what became known, rather pejoratively, as the "American" rule: a physician must inform his patients of all the risks and benefits of the proposed treatment, and such information about the alternatives as a reasonable patient would want to know in order to make an informed rational decision. Essentially, this represents the standard adopted in 1972 in *Canterbury* v. *Spence,*[3] the leading American case, which now forms the basis of the law in many states.[4]

The defendants contended that the standard ordinarily applied in medical malpractice cases, and in all negligence cases, ought to be applied in this situation. The defendant physician, they argued, should be liable only if *no reasonable physician* would do what the defendant did, namely seek consent to the laminectomy without informing the patient of all material risks. This "reasonable doctor" or "ordinary negligence" standard is still applied in some American jurisdictions.[5] Whether the "American" rule is, in fact, the majority rule in the United States depends upon how ambiguous decisions are counted; each rule provides the law in several states on this side of the Atlantic.

The "American" rule is patient oriented: it looks to the plaintiff's need or desire to know. The "ordinary negligence" rule is physician oriented; it looks to the conduct of the reasonable physician. Under either rule, the patient would be able to recover only if the failure to inform was the *cause* of the patient's apparent consent to the procedure. In this case, the judge found that:

> . . . if [Mrs. Sidaway] had had the nature of the operation fully explained to her, and been told of the small but appreciable risk of spinal cord damage, she would not have consented to undergo the operation when she did. . .

The trial court judge was squarely faced with the alternative legal theories: the "American" rule would unquestionably lead to a judgment for Mrs. Sidaway; the ordinary negligence rule would unquestionably lead to a judgment for the defendants. Finding that "there is a clear divergence between the English decisions and the transatlantic cases, . . . [and] I am bound by the former" the judge applied the ordinary negligence rule and decided for the defendants. The judge's findings of fact put the legal question so starkly that Mrs. Sidaway challenged his view of the law in the Court of Appeal.

The Court of Appeal

The Court of Appeal unanimously affirmed the judge's decision. The three-judge panel left no doubt that their judgments were based as much on the difference between British and American medicine as they were on the difference between English and American law. Sir John Donaldson, the Master of the Rolls (President of the Civil Division of the Court of Appeal), admitted that the courts would not

> stand idly by if the profession, by an excess of paternalism, denies its patients a real choice. In a word, the law will not permit the medical profession to play God.

But, in limiting physicians to their priestly ministrations, he leaves no doubt about where good sense would place decision-making authority:

> A doctor's duty of care, as the profession would readily concede, involves his evaluating risks and weighing advantages and disadvantages before recommending a particular type of treatment. But, having decided what to recommend, there must be a natural, and up to a point, praiseworthy desire that the advice shall be accepted and a strong temptation not to say anything which might lead to its rejection and so frustrate the doctor's prime object, which is to maintain and improve the patient's health.

Lord Justice Dunn, in concluding that "[t]he doctrine of informed consent form[ed] no part of English law," explained that

> [i]t is doubtful whether [informed consent] would be any significant benefit to patients, most of whom prefer to put themselves unreservedly in the hands of their doctors. This is not in my view "paternalism," to use an evocative word used in argument. It is simply an acceptance of the doctor/patient relationship as it has developed in this country.

The Court of Appeal reviewed *Canterbury* v. *Spence* with a scrutiny unmatched by any of the American decisions that have applied it. The *Canterbury* court's almost imperceptible slide from a theory of battery to one of fiduciary duty and then, finally, to one based on negligence did not enhance the status of the United States Court of Appeals in its English counterpart. Through very careful analysis of the authorities cited in *Canterbury,* the English courts have admitted what most American courts have neglected to say—*Canterbury* represents a real departure from the previous law. Even if its result was based upon sound policy, it did not flow from well-established law. It was, as Lord Scarman put it in argument in the House of Lords, a "bold step."

House of Lords

The Court of Appeal permitted Mrs. Sidaway to appeal her landmark case to the House of Lords. The oral argument left little doubt that the House of Lords would not give a secure harbor to a transatlantic crossing of the "American" doctrine of informed consent. During the oral arguments the Law Lords frequently pointed out that the status and protection of the medical profession were relevant considerations. They contrasted the relationship of the two professions in England with the travail visited upon American physicians by the judicial scrutiny of medical decisions through the doctrine of informed consent, but made no attempt to evaluate the effect the doctrine has had upon American medicine. It was simply assumed that the effect had been adverse. It was no surprise, therefore, that the House of Lords dismissed the appeal.[6]

All but one of the Law Lords rejected the *Canterbury* test, and four of the five panel members delivered separate opinions, Lord Bridge recognized the "logical force of the *Canterbury* doctrine, proceeding from the premise that the patient's right to make his own decision must at all cost be safeguarded against the kind of medical paternalism which assumes that 'doctor knows best'. . . ," but he regarded the *Canterbury* test as "quite impractical." In his view it gave too little scope for the doctor's clinical judgment; it deprived the court of the benefit of expert evidence when determining which risks should be disclosed; and it was "so imprecise as to be almost meaningless." Although Lord Bridge superficially rejected "medical paternalism," he really embraced it by failing to follow the *Canterbury* decision. Any ambiguity in Lord Bridge's approach was dispelled when he said:

> . . . that a decision [concerning] what degree of disclosure of risks is best calculated to assist a particular patient to make a rational choice as to whether or not to undergo a particular treatment must primarily *be a matter of clinical judgment.* [emphasis added]

Most of the court considered the doctor-oriented "reasonable doctor" test, with its reliance on expert medical evidence of professional practice, a more appropriate yardstick. Lord Diplock summed up the majority's position:

> The only effect that mention of risks can have on the patient's mind, if it has any at all, can be in the direction of deterring the patient from undergoing the treatment which in the expert opinion of the doctor it is in the patient's interest to undergo. To decide what risks the existence of which a patient should be voluntarily warned and the terms in which such warning, if any, should be given, having regard to the effect that the warning may have, *is as much an exercise of professional skill and judgment as any other part of the doctor's comprehensive duty of care to the individual patient, and expert medical evidence on this matter should be treated the same way*. . . [emphasis added]

In England the "reasonable doctor" test has often made it very difficult for a plaintiff to establish negligence against a doctor in a medical malpractice action. Compliance with a procedure, treatment, or diagnostic process accepted by a competent body of medical opinion *will not* be negligent even if other members of the profession would not have followed the defendant's action.[7]

Does this mean that expert medical evidence of professional opinion will conclusively determine a doctor's legal duty? Lord Diplock considered that such evidence would be conclusive. However Lord Bridge (with whom Lords Keith and Templeman agreed) did not regard the "reasonable doctor" test as necessarily "hand[ing] over to the medical profession the entire question of the scope of the duty of disclosure. . ."[8]

Lord Bridge gave two illustrations of the court's role. First, the court would resolve any conflicting expert evidence of whether a responsible body of medical opinion did approve of nondisclosure. But any testimony by any "responsible" physician that he would not disclose a particular risk would appear to meet the doctor's evidentiary burden. Thus, it is difficult to imagine the conflict of expert evidence that Lord Bridge discussed ever arising unless the defendant was alleged to be practicing "quack" medicine.

Second, even if such a body of opinion did exist, the court could nevertheless regard nondisclosure in accordance with it negligent where "an operation involved a substantial risk of grave adverse consequences, as, for example, the ten percent risk of a stroke from the operation which was the subject of the Canadian case of *Reibl* v. *Hughes*. . ." But even this would not be so if "cogent clinical reasons" existed for nondisclosure. What legal standards the courts might employ to determine whether a responsible body of medical opinion was improper, or whether any "clinical reasons" were sufficiently "cogent," was left unexplained. Rarely will a court be in a position to "second-guess" the medical profession and so the exercise of the residuary power to override professional opinion will be exceptional. Even on the exceptional facts of this case, Lord Bridge saw no reason to do so.

The Majority's decision to reject the *Canterbury* approach must be seen in the context of the differing processes of judicial reasoning in America and England. In America, with a written constitution and bill of rights, legal remedies can be derived from *rights* (here, the rights of patients). In England, with no written set of broad and fundamental principles and a tradition of stricter reliance on precedent, legal remedies can be derived only from previously defined *duties* (here, duties of physicians). Necessarily, American law can be rights-(and, thus, patient-) oriented while English law has to remain duty-(and, thus, physician-) oriented.

Only Lord Scarman threw off the shackles of the traditional English approach:

> The doctor's duty arises from his patient's rights. If one considers the scope of the doctor's duty by beginning with the right of the patient to make his own decision whether he will or will not undergo the treatment proposed, the right to be informed of significant risks and the doctor's corresponding duty are easy to understand: for the proper implementation of the right requires that the doctor be under a duty to inform his patient of the material risks inherent in the treatment.

The "right to self-determination" could be said to require disclosure of all risks which a *particular patient* would want to know but, as Lord Scarman remarked, while this might be the doctor's ethical duty, it could not be his legal duty because the law did not operate in Utopia and this subjective approach would be "frustrated by the subjectivity of its aim and purpose." Instead Lord Scarman approved the "prudent patient" test of *Canterbury.*

Even a patient-oriented test requires exceptions. In America, waiver, incompetence, and "therapeutic privilege" have been accepted.[9] In *Sidaway* Lord Scarman recognized the last exception:

> A doctor may avoid liability . . . if he can show that he reasonably believed that communication to the patient . . . would be detrimental to the health (including, of course, the mental health) of the patient.

The "therapeutic privilege" exception, like that of waiver, furthers the autonomy or the "right to self-determination" of the patient because it enhances his ability to choose by denying him the information that would *impair* his ability to make an informed choice.

In the end, even Lord Scarman determined that Mrs. Sidaway had not met her burden of proof by showing that the small risk of serious injury was the kind of risk of which a "prudent patient" would wish to be apprised. It is hard to imagine what additional evidence could have been adduced to allow Lord Scarman to determine whether the risk was "material." The important consequence of the *Sidaway* case may be found not in the confusing and diverse reasons for the result but in the realization that even on the relatively clear facts of this case all five Law Lords ultimately felt obliged to leave the decision in the hands of the physician.

The House of Lords' decision is the final judicial determination of the issue. Parliament is extremely unlikely to intervene to change the law. Although their Lordships unanimously dismissed the appeal, their reasoning lacks any such unanimity.

The Social Climate

The Law Lords' approach grows out of a long tradition of highly paternalistic medicine, an attitude vigorously attacked by Professor Ian Kennedy in *The Unmasking of Medicine* (1983). The tradition is supported by the social class differences between most patients and their physicians and the greater significance of these differences in the United Kingdom. As the proceedings in *Sidaway* indicate, the legal profession defers to its medical counterpart as a part of the tacit agreement to respect the traditional distribution of social power. English lawyers are not perceived by English doctors as adversaries because they are social classmates, cohorts, and friends. Unlike American professional education, English medical and legal curricula are largely undergraduate programs. Unlike the differences between Socratic law classes and didactic medical classes, the forms of education offered to English medical and law students are broadly similar.[10] Thus, it was easy for the Law Lords, who appeared to have no trouble understanding the medical procedures in the *Sidaway* case, to discuss in argument how difficult it would be for any patient to understand those same procedures.

In addition, there may be less need for malpractice litigation and, particularly, its most symbolic manifestation—informed consent litigation—in a society where there is a well-developed welfare system. Mrs. Sidaway, although uncompensated for her pain and suffering, is at least partially protected from the loss of income that resulted from her surgery. The National Health Service will provide all the subsequent medical care she requires without charge.

DeFacto Rationing and Informed Consent

Even in the absence of these factors, informed consent probably could not become a recognized part of medical practice in England. Ultimately, the existence of a national health system, prospectively funded by a central planning authority, and with limited and defined resources, makes the acceptance of such a doctrine an impossibility. The 1984 edition of the British Medical Association's "Handbook of Medical Ethics" states:

> Within the National Health Service resources are finite, and this may restrict the freedom of the doctor to advise his patients, who will usually be unaware of this limitation. This situation infringes the ordinary relationship between patient and doctor . . . (paragraph 10.44)

Because the system cannot tolerate the financial effects of all reasonably possible patient decisions, it cannot tolerate the doctrine of informed consent. The handbook continues: "Patients will seek advice . . . where the doctor believes treatment to be desirable; however, because of limited resources, such treatment may not be available . . . within the NHS." By contrast the American health care system may be structured in such a way that it can more readily embrace the doctrine of informed consent.

While the American health care system is hardly a paradigm of the open market, it does have many of its attributes. Although the widespread existence of health insurance may cause some patients to ignore the high cost of medical care, that care is not always overused for that reason. Patients are unlikely to choose kidney dialysis, for example, or heart bypass surgery, just because they enjoy being consumers. Even if owning more cars is always better than owning fewer (you can sell off the ones you do not use), more time on a respirator is not always better than less. Further, recent use of the antitrust laws to increase competition between health care institutions, and proposals to encourage large deductible and copayment elements within medical insurance schemes, indicate that something closer to a market for health care may develop. The decades-old discussion of what American national health insurance would look like has given way to discussion of how to bring the economics of the marketplace to health care.

Within the market for medical services, as within any market, the consumer makes the choice of allocating resources. Even when the doctor prescribes and the insurance company pays, the patient is the consumer. As the model requires, the patient will decide the nature of the medical care to be provided. If a patient arguably suited for kidney dialysis wants kidney dialysis, and if he can pay for it, the patient is likely to get kidney dialysis. Because, in fact, patients *can* pay for kidney dialysis in the United States (albeit only with a good deal of government intervention in the market), those patients who might be able to benefit from dialysis will be told of that possible treatment, and will be able to choose to undergo it.

The patient's choice of treatment will determine not only the allocation of health care resources, but the portion of all resources that will be allocated to health care. For example, if more patients want dialysis, or heart bypass surgery, or more expensive forms of cancer screening, or more active intervention upon their seriously ill newborns, they will get it. In those four areas the availability of health care in the United States dwarfs the reduced level of services available in Britain. If patients are willing to spend more on health care (and health insurance) and less on cars and skiing, a greater portion of the nation's resources will be directed toward health care. As Charles Fried argued six years ago, "The one sure way to determine what the proper level of health care consumption is" must be "consumer choice."[11]

Thus, at least in those areas generally covered by insurance schemes (and those same areas generally end up covered by government programs designed to aid those without insurance), the economics of the health care system allows room for consumer choice. This consumer choice in the health care market, and the subsequent "consumer sovereignty," stem from precisely the same principles that give rise to the doctrine of informed consent, which, after all, only assures that consumer choices wil be appropriately made. Consumer choice and the doctrine of informed consent arise out of notions of self-determination and autonomy. Even the President's Commission, which recommended shared physician/patient decision making, recognized that

> in the context of health care, self-determination overrides practitioner-determination even if providers were able to demonstrate that they could (generally and in a specific instance) accurately assess the treatment an informed patient would choose.[12]

In reaching this determination, the Commission depended on Gerald Dworkin's recognition that of all of the foundations advanced as support for the doctrine of informed consent—privacy, self-determination, loyalty, autonomy, freedom, integrity, dignity, and medical benefits—the core notion is one of autonomy.[13]

Simply stated, the economic principle of "consumer sovereignty" and the underlying notions of autonomy and self-determination are recognized in medical law through the principle of informed consent, which allows patients to choose which treatment to undergo and which to forego. There can be no "consumer sovereignty" except within a system that recognizes the doctrine of informed consent, and there is no informed consent where the patient-consumer cannot have a choice of health care options.

The economics of the British National Health Service could not tolerate providing patients with real authority to choose health care. Compared to the United States, Britain spends about half the percentage of its already lower gross national product on health care. Obviously, that system could not afford the medical care choices that are being made in the United States.

A decision to provide some particular medical procedure within the National Health Service does not allocate more of society's resources to health care; that allocation has already been made. A decision to spend *l*10,000 on one case necessarily means that *l*10,000 less will be spent to provide health care to others. The question of whether terminally ill and comatose patients should be maintained is not often discussed across the Atlantic; there simply are not the financial resources to permit patients' families to decide the issue. Similarly, while the United States has ninety dialysis places per million population, Britain has only thirty-three.[14] This differences does not represent a population with dramatically different medical diagnoses; rather, some patients who would need (and get) dialysis in the United States are not offered it in England.

The National Health Service is required by law to provide all health care services necessary "to meet all reasonable requirements."[15] Thus, it is politically and legally difficult for the Government to admit that resources are insufficient to meet the medical needs of the country, although on rare occasions implicit financial limitations have been explicitly recognized. In 1980, in *R.* v. *Secretary of State for Social Services, ex p. Hincks,*[16] the Court of Appeal heard orthopedic patients claim that lack of hospital facilities in a particular center had caused them to wait for treatment longer than was medically advisable. In dismissing their claim, the Court of Appeal emphasized the limited resources available to the Government. The trial judge put it thus:

> It all turns on the question of financial resources. If the money is not there then the services cannot be met in one particular place.[17]

While the law can recognize and validate the postponement of orthopedic treatment, the fatal consequences of not providing dialysis have made it impossible for the National Health Service to admit that this life-sustaining treatment would ever be denied because of inadequate resources.[18] Since formally articulated *de jure* rationing is impossible, the health care system must allocate its limited resources through some *de facto* rationing process.[19] The decentralized nature of the National Health Service, combined with the medical profession's consistent demand that it be the sole arbiter of medical questions, have put the burden of allocating resources upon individual practitioners and medical specialists.

While each physician has an obligation to his patients, he also bears some obligation to the health care of the nation as a whole. Specialists, who control the most expensive technologies, are likely to be especially protective of their resources since they are in a position to predict who will be denied those resources if a particular patient gets them. A physician knows that for each patient who receives dialysis, somebody else will not. In his role as a physician, he is obliged to explain to his marginal dialysis patient what the risks, benefits, and alternatives to dialysis would be. In his role as allocator of health services, he is obliged to see to it that the marginal patient is not provided with dialysis. Because the alternative to such treatment is usually death, it is hard to imagine how a physician who must, as the system requires, play the second role can possibly play the first adequately.

The only way that physicians can allocate scarce services is to decide that the patient is not a candidate for those services—in this case, dialysis—and thus should not be offered the option. To accomplish that, a physician must change some of the attributes that, if there were sufficient services for all who might want them, would be considered personal values to be weighed by the patient, into medical criteria to be evaluated by the doctor. For example, doctors consider certain "quality-of-life" factors such as mental and physical disability, family supportiveness, and ability to communicate (in the language of the doctor, of course) as medical factors in determining whether dialysis is appropriate.[20] Similarly, many patients are not offered a choice of dialysis because they are diabetics or over fifty-five years old.

Because the unspoken *de facto* rationing is done by physicians alone, they must define the issues as narrow medical questions, not suitable for general public discussion. As the President of the British Kidney Association explained following the highly publicized recent "rescue" of a mentally and physically ill "difficult" dialysis patient whose treatment was discontinued in January:

> Decisions not to treat kidney patients are being taken by doctors all the time. Usually the patient does not understand that he could have been treated and goes away to die quietly.

Of course, informed consent and patient autonomy are not always expensive principles that require a claim on scarce health care resources. In the United States controversy has flared over terminally ill patients' rights to refuse such expensive treatment as chemotherapy and dialysis. The recognition of patient autonomy will allow these patients to choose to forego treatment, if they choose, with a consequent saving of money. In a closed, prospectively funded system, these funds would be reallocated to other medical care. Nevertheless, while deference to patients' wishes may save some funds, it results in an unpredictable level of health care demands, which makes health care planning very difficult.

In many of the most controversial areas, such as those touching upon supportive care for the terminally ill or seriously ill newborns, the British medical profession has already chosen the cheaper path—apparently as a matter of medical judgment. In other areas, such as Mrs. Sidaway's back troubles, a decision against expensive therapy may only delay the necessity for even more costly and longer term health care. If health care decisions were, in fact, patient decisions, there would be no way to achieve the centralized financial planning that is one of the necessary and stabilizing characteristics of the National Health Service.

The value attached to patient participation in medical decision making within the National Health Service cannot be as great as the value attached to it when the patient is likely to pay for the consequences of his decision. The National Health Service cannot afford the caprices of individual patients who choose medical care that leads to an improper allocation of the community's health care resources. The collective health of the nation cannot be held hostage by a few who wish more expensive treatment. There cannot be consumer sovereignty, and, thus, there cannot be as much respect for patient autonomy and the doctrine of informed consent, within a financially closed system.

Because allocation decisions, which are implicitly patients' decisions in the United States, must become doctors' decisions in the United Kingdom, there cannot be the same legal or social recognition of the primacy of patients' rights to make relatively free, unfettered, and informed choices about alternative therapies. The increasing number of Americans who are cared for through prepaid health maintenance organizations may face this same kind of limitation on the range of available alternative therapies. Instead of the British importing the American doctrine of informed consent, Americans might well import the British dilemma posed by rationing health care in a society premised on patient sovereignty.

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The Courts Are Speaking; Is the Medical Profession Listening?

WILLIAM L. TROMBETTA, J.D., Ph.D.

In 1982, the Supreme Court continued its recent series of professions-affecting decisions when it handed down *Arizona v. Maricopa County Medical Ass'n.*[1] As one would expect a Supreme Court decision to do, it generated a deluge of articles not just on substantive aspects of antitrust law but also on its implications for the health care field.

If one had bothered to read the commentators who had something to say about *Maricopa*, one would have thought that its significance was limited to the following points: (a) antitrust law definitely applies to the professions; (b) once per se[2] unlawful conduct (such as price fixing) is established, no proposed justifications will be entertained; (c) the courts need not be familiar with an industry to find conduct per se unlawful; (d) it is per se unlawful for competing professionals to agree on a maximum price above which they will not charge; and (e) upon a showing of sufficient sharing of risk and pooling of assets, otherwise independent competitors can constitute a new business entity formation wherein they no longer compete with each other but operate as a single firm that competes with other sellers in the market.

While the literature and commentary have emphasized the above noted points, the courts are beginning to cite *Maricopa* for a different proposition—"public service and ethical norms"—particularly, where price fixing is not in issue. The Supreme Court noted that the defendants in *Maricopa* did not argue that their pricing arrangements enhanced the quality of health care:

> The price fixing agreements...are not premised on public service or ethical norms. The respondents do not argue...that the quality of the professional service that their members provide is enhanced by the price restraint.[3]

Hence, the most profound impact of *Maricopa* may be yet to come, namely, substantiating that conduct which incidentally restrains trade is "premised on public service or ethical norms."

For example, supposed anticompetitive restraints on medical staff access or on the scope of professional practice which foster "public service and ethical norms" may be able to withstand scrutiny. At the very least, claims premised on "public service and ethical norms" that are buttressed by substantiation would most likely result in even group boycott conduct being taken out of the realm of per se and evaluated under the rule of reason giving a defendant a considerable litigation advantage.[4]

Reconciling *Maricopa* With Earlier Supreme Court Cases

The *Maricopa* Court's references to earlier Supreme Court cases[5,6] for the implication that non-competition criteria such as "public service and ethical norms" might have saved the day for the *Maricopa* defendants is not without irony. *Maricopa* was a price fixing case as were *Goldfarb* and *Professional Eng'rs.* Despite arguably laudable professional ethics and public service arguments made by the defendants in those two cases, the Supreme Court found unlawful price fixing. Hence, it is not clear how or why arguments based on "public service and ethical norms" could or even should have made any difference in *Maricopa* given the legal precedent established by these decisions.[7,8] This frequently cited "footnote 17" provides the moral underpinnings for claiming special treatment under antitrust examination.

The professional trade association in *Professional Eng'rs.* defendants argued that competition itself is undesirable because it allegedly results in shoddy work and danger to public safety. This argument was soundly rejected by the Court. A private group simply cannot set

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itself up as an arbiter of whether competition is desirable or not.

However, conduct that restrains trade or that has some anticompetitive spillover may still be permissible if the quality of service is enhanced. Also, challenged conduct may pass muster if the basis for a restraint originates in the marketplace, i.e., "pulled" through the demand of the buying public rather than pushed by a supposed self-serving provider group. If the demand for or preference for a particular kind of activity or practitioner category genuinely exists in the market, then a free enterprise response to that demand should not be penalized.

For example, the District Court for Western Pennsylvania in *Robinson v. Magovern*,[9] a medical staff privileges case, made much of the fact that Allegheny General Hospital, one of the defendants, had formulated objectives and a competitive strategy in response to a well known management consulting firm's study conducted well before the litigation at hand arose.[10] In essence, the defendant hospital was able to prove that it wanted to be the best that it could be in providing a "true standard of excellence in patient care" based on achieving high quality graduate medical education and research.[11] The court went on to state:

> Allegheny General's strategy for marketing . . . medical services is intimately connected with its institutional objectives. . . . the Trustees believe that a reputation for excellence and innovation in medical care will attract patients, both directly and through referrals. Prospective patients and referring physicians will *perceive* an institution whose staff provides formal instruction for young doctors as an institution that has a commitment to excellence in the delivery of medical services and has the talent available on the medical staff to fulfill that commitment. Likewise, they will *perceive* an institution whose staff participates in medical research as an institution that will provide its patients with care that incorporates the latest advances in medical science.
> . . . . Thus, for the past fifteen years, Allegheny General has anchored its marketing strategy on the proposition that a regional referral hospital will attract large numbers of patients if it develops a reputation for high quality programs in patient care, teaching and research.[12]

The emphasis has been added to underscore the significance of the fact that the defendants in this case did not merely conclude that they know what is best for the consumer. Rather, they had an outside consultant research the needs of the marketplace in terms of consumer and referring physicians' perceptions. Then, they developed and implemented a competitive strategy that enabled the hospital to compete more effectively by seeking to capitalize on those perceptions. The court ruled that the hospital's rejection of the plaintiff-doctor's staff application, based on input from its medical staff, was not "[inconsistent] with the hospital's institutional objectives or competitive strategy."[13]

Similarly, in the mid-1970's, Century 21, the largest real estate franchisor in the country, sought only Realtors for franchisees. Century 21's motive was based on the unsubstantiated premise that the public prefers to deal with Realtors rather than mere licensed real estate brokers.[14]

An analogy would be a law firm that limits its hiring to the top law schools or a corporation that recruits from only the elite MBA programs. Of course, those unable to gain employment under such criteria would still have an overwhelming portion of the market available to them in seeking jobs. Hence, the impact would be miniscule relative to the marketplace effect in certain health care contexts. Nonetheless, the Supreme Court language and recent lower court interpretations and applications suggest that the ability to demonstrate marked improvement in benefits to the consumer will be given serious consideration in regard to antitrust challenges.

Clearly, those parties advocating conduct that is based on legitimate concern over the delivery of health care will have a heavy burden. The time to begin documenting and substantiating "public service and ethical norms" enhancement is *prior to* litigation, not after a lawsuit is filed.

With this premise in mind, we now turn to an examination of the circumstances, analogous contexts and precedents that may serve as the basis for developing means in order that preventive steps can be taken to enable those with genuine professional and quality health care concerns to take positions with respect to restricting the scope of practice of certain health care providers or excluding a certain category of health care provider entirely without automatically being branded as monopolists or conspirators.

The Legal Context

As noted earlier, group boycotts are an especially pernicious type of unlawful antitrust conduct precluding any attempt to explain the conduct or give reasons for it. Yet, an inquiry into the "good faith" of a group of defendant doctors was conducted by the court in *Feminist Women's Health Center, Inc. v. Mohammad.*[15] The issue before the court was whether the services provided by a local health care clinic to its abortion patients were adequate, and, if not, whether local doctors acted properly in withdrawing their services from the clinic and discouraging other doctors from performing abortions at the clinic. The clinic claimed that the doctors intended to destroy the clinic's abortion services, which were priced significantly lower than those offered by surrounding doctors. The court ruled that the doctors' claim of "good faith" could be a defense. In a strictly commercial context, such conduct would have called for a per se application; i.e., attempts to justify the collective withdrawal of the doctors' services would simply not have been considered.

In a similar case, the plaintiff doctor claimed that he was the victim of a group boycott when the defendants refused to refer patients to him.[16] Relying on *Goldfarb, Professional Eng'rs.*, and *Maricopa*, the court invoked the

Maricopa "public service and ethical norms" language in ruling that conduct of hospitals and doctors which appears to resemble a group boycott may well be mandated by an ethically grounded concern for patient well-being.[17] The court refused to apply the per se standard thereby placing the plaintiff in the difficult position of having to prove that any anticompetitive effects associated with the refusal to refer patients outweighed any procompetitive effects under the rule of reason standard.

In *Weiss v. York Hospital,* the Third Circuit affirmed that the defendant medical staff discriminated against osteopathic doctors regarding hospital staff privileges. The particular egregiousness of the defendants' conduct toward osteopaths in this case is signified by the rare application of the per se standard to conduct other than price fixing in a health care context.[18]

The defendants never argued that they were entitled to exclude individual doctors, including osteopaths, on the basis of their lack of professional competence or unprofessional conduct:

> [Defendant] has not contended that osteopaths as a group are less qualified than M.D.s. . . . In the absence of such a contention, or another legitimate explanation for the discrimination, we conclude that a *per se* rule should be applied, since the effect of the practice is identical to that of the traditional boycott, and plainly anticompetitive.[19]

The court also noted that the *York* defendants did not argue that their conduct was justified on "public service or ethical norms" grounds.[20]

The inference is unmistakable. This article is not intended to debate the merits of any practitioner group's qualifications to practice medicine. The point is that had the *York* defendants made a colorable claim of legitimate concern over patient well-being, the rule of reason would have been applied instead of the per se rule making it much more difficult for the plaintiff to prove his case.

The Seventh Circuit recently ruled on a "public service and ethical norms" defense.[21] In that case a professional dental society refused to comply with a group dental health plan insurer's directive to submit copies of a patient's X-ray along with the patient's insurance claim form. The FTC claimed this refusal was a group boycott. The Seventh Circuit applied the rule of reason and reversed the Administrative Law Judge and the FTC holding that the FTC failed to establish any anticompetitive effect.

The defendant dentists argued that more was involved in evaluating proper dental treatment than merely the patient's X-ray and his insurance form. Complete patient records as well as diagnostic procedures in the dentists' offices were made available to insurer representatives to facilitate a proper evaluation.

The appellate court noted that the dentists' collective refusal was based on the dentists' adherence to a legal, moral and ethical policy of concern for providing quality dental care. This quality dental care policy was reinforced and substantiated by the American Dental Association code of professional conduct and the Indiana Federation of Dentists' dental code.

The compromise or meeting halfway aspect of this opinion is also noteworthy. The dentists' conduct was not construed as a complete refusal to deal; rather, the court characterized it as doing business on the dentists' terms in compliance with established, accepted and appropriate standards of quality dental care.

With respect to documentation and empirical substantiation, the court placed the shoe on the other foot in holding that the FTC fell short in its proofs. The FTC offered no evidence that submission of patients' dental X-rays actually lowered the insurers' dental costs or that refusals to submit copies of x-rays actually increased dental costs.

The most recent "public service and ethical norms" case involved a trade restraint that resulted from by-law provisions. In *Aron v. Michigan Health Care Corp.*,[22] the plaintiff doctor specialized in orthopedic surgery, as did the defendant doctor who was an "active" member of the defendant hospital's staff. The plaintiff entered into a contract as an employee of the defendant doctor and he became a "provisional" member of the defendant hospital's staff. A by-law provision required that all initial appointments are for one year. During that time the new doctor's admissions and procedures are monitored and observed by a member of the Active Medical Staff. Active members can delegate emergency room referral calls to another doctor with at least temporary privileges. This applies to provisional members if they are the only representatives of their specialty. The plaintiff received such referrals while employed by the defendant doctor as a provisional staff member.

The plaintiff and the defendant doctor had a falling out. The plaintiff claimed that the defendant made false representations about him. The defendant doctor then stopped his referrals to the plaintiff. The plaintiff was still a provisional member at the defendant hospital but he no longer received emergency room referrals from the hospital unless a patient specifically requested him. The plaintiff challenged this restraint as an antitrust violation.

The court stated that the by-law provisions themselves are neutral.[23] The court held that a one year observation/monitoring period appears reasonable and legitimate to attempt to control quality. The court went on to observe that although the plaintiff "appears on paper to be both experienced and qualified has no effect on the hospital's right to observe all provisional staff members as a part of its evaluation process."[24]

The *Aron* Court paid homage to the emerging "public service and ethical norms" standard:

> In the area of physician referrals and staffing decisions, behavior which might in a normal commercial sphere be considered a group boycott subject to per se rules may

well be dictated by public service and ethical norms, and as such would not be subject to per se.[25]

Realtors have had their share of run-ins with antitrust law, particularly involving the real estate counterpart to medical staff privileges—Multiple Listing System (MLS) access. In *Marin County Bd. of Realtors v. Palsson,*[26] the Realtor board brought an action seeking a declaratory judgment that its denial of membership to a part-time real estate broker was valid. One of the board's proposed justifications for the conditions on MLS access was that such restraints foster professional competence and ethics of real estate brokers. The California Supreme Court accepted the legitimacy of the goal but ruled that the board failed to demonstrate or substantiate that the restrictions on MLS access served to enhance professional competence or ethics.

Having demonstrated the increasing appearance of the "public service and ethical norms" and enhancement of quality standard, we now turn to a brief overview of some approaches that have been used for demonstrating what appear to be, at first, the ephemeral, non-quantifiable characteristics of the standard. A good starting point is a 1979 study comparing legal clinics to traditional or conventional law firms in Los Angeles on a number of performance measures.[27]

Just as the debate continues concerning the relative competencies among intra-groups of providers (e.g., M.D.'s v. D.O.'s) and inter-groups (e.g., M.D.'s v. Chiropractors v. allied health practitioners), the issue in this research concerned the relative competencies between "low cost" law clinics and the more traditional full service, high priced, "prestige" law firms.

The authors examined the effect of advertising on the quality of legal services offered at lower prices by the clinic. Two approaches, one subjective, the other objective, were employed. Using mail survey forms, respondents identified lawyers who provided them with service. This information was used to separate clinic clients from conventional law firm clients. The authors then applied a number of statistical techniques to empirical data to determine which kind of legal service provider, the law clinic or the traditional law firm, was the higher quality provider.[28]

The authors concluded that despite charging lower prices, the clinic was not perceived as providing lower quality services. This conclusion was affirmed in the objective test as well. In fact, on some measures of quality, the law clinic's services were demonstrably better than those of conventional law firms providing the same services. This kind of approach can be applied to a *Robinson v. Magovern* situation (discussed earlier) to determine the significance of differing consumer perceptions and images of different classes of health care providers over key performance measures.

Hence, "public service and ethical norms" and the enhancement of quality of health care are not merely abstractions or high sounding opinions. They can be strived for, attained and measured. The time to begin developing these kinds of working hypotheses and empirical data banks is now, not after a lawsuit is filed. Conclusory but unsubstantiated opinions claiming that one camp of providers is either superior or inferior to another are likely to be increasingly viewed with skepticism as the vented frustrations of those with a vested interest in preventing further encroachment upon their respective turfs. On a positive note, the courts are signaling that genuine concerns over who can practice or provide what kinds of medicine and health care under what terms and conditions will be accorded a fair hearing but only if supported by empirical substantiation and documentation. Legal precedent such as *Robinson v. Magovern, Indiana Fed. of Dentists v. FTC, Aron v. Michigan Health Care Corp.*, and *Marin Cty. Realtors v. Palsson,* and research articles in the literature on statistical techniques and methodology point the way to conduct and accomplish such substantiation.

Conclusion:
Implications for the Medical Profession

It appears that the courts are willing to meet the medical profession halfway concerning the tension resulting from a rapid infusion of competition into the marketplace on the one hand and legitimate interests in the provision of quality health care on the other. As to the latter, at least five recent court decisions in addition to a United States Supreme Court opinion signal a willingness to accept health care quality and ethics concerns as a defense to[29] antitrust challenges if these concerns can be validated.

Another significant implication is that after *Robinson v. Magovern,* the importance of a strategic business plan for purposes beyond just management cannot be gainsaid. The *Robinson* Court could not have been more explicit in underscoring the significance of the fact that the hospital had research conducted to determine the needs of the marketplace in terms of consumer and referring physicians' perceptions. Then the hospital developed and implemented a competitive strategy that enabled it to compete more effectively by seeking to capitalize on those perceptions. The court ruled that the hospital's rejection of Dr. Robinson's staff application was not "inconsistent with the hospital's institutional objectives or competitive strategy." Hence, *Robinson v. Magovern* reflects the importance of a strategic business plan that extends beyond just management. Those kinds of decisions and activities that can give rise to antitrust risks (e.g., credentialing/staff privileges) may be defused somewhat by careful planning that sets legitimate objectives which can be empirically substantiated.

The key question in health care antitrust confrontation will be the nature of the conduct at issue. Anything short of price fixing, even group refusal to deal matters, will most likely be evaluated under the rule of reason standard if genuine concerns for public service, ethics and quality of care can be established.

The medical profession stands to gain a great deal from a "public service and ethical norms" standard applied to health care trade restraint challenges. More reliance on quantitative analysis and empirical substantiation complement this emerging standard. The courts are speaking, is the medical profession listening?

REFERENCES

1. 457 U.S. 332 (1982). The Supreme Court applied the per se rule in determining that a classic form of price fixing, maximum fee schedules, required by participating doctors' contracts with medical care foundations was illegal.
2. There are certain practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm caused or justification. If it is determined that the conduct falls within the prohibited category, the application of the per se rule ends the antitrust inquiry in a finding of illegality by merely establishing that the conduct occurred.

   Other than a handful of egregious classes of trade restraints, most antitrust challenges are evaluated under the rule of reason. This standard calls for time consuming and extensive efforts in balancing procompetitive effects against anticompetitive effects to determine which outweighs the other, and definitely favors a defendant in terms of going forward with the case.
3. Id. at 348-49.
4. Group boycott or concerted refusal to deal is one of those few categories of anticompetitive conduct that is generally accorded per se treatment. For example, see *Weiss v. York Hospital,* nos. 82-3507, -3580, & -3581 (Sept. 27, 1984) slip opin. ' pp. 66-75. Group boycott or concerted refusal to deal refers to at least two or more competitors agreeing with each other to collectively exclude or collectively not deal with another competitor or a particular class of customers.
5. Goldfarb v. Virginia State Bar, 421 U.S. 773 (1975).
6. National Soc'y of Professional Eng'rs. v. United States, 435 U.S. 679 (1978).
7. Even as early as 1975, the Supreme Court acknowledged that the professions may warrant different treatment when they engage in conduct that commercial businesses undertake. In Goldfarb, the Virginia State Bar Association was found liable for price fixing under the Sherman Act for setting a minimum fee schedule for "routine" legal services such as title searches. Although the Court rejected a learned profession exemption from the Sherman Act, Chief Justice Burger stated in a footnote to the majority opinion:

   > It would be unrealistic to view the practice of professions as interchangeable with other business activities, and automatically to apply to the professions antitrust concepts which originated in other areas. The public service aspect, and other features of the professions, may require that a particular practice, which could properly be viewed as a violation of the Sherman Act in another context, be treated differently.

   Goldfarb, supra, at 788 n. 17.
8. Professional Eng'rs. was even more confusing. On the surface, a professional trade association's canon of professional ethics forbidding competitive bidding by engineering firms was held in violation of the Sherman Act, presumably a per se violation tantamount to price fixing. Yet, the Court went on to such great lengths in evaluating the challenged restraint that the Court could easily have been and has been described as applying a rule of reason standard to conduct virtually identical in effect to bid rigging. Professional Eng'rs, supra, at 687-692.
9. 521 F. Supp. 842 (W.D. Pa. 1981).
10. Id. at 850, 859, 919, 920, and 927.
11. Id. at 859.
12. Id. at 860 (emphasis added).
13. Id. at 859.
14. The New Jersey Real Estate Commission required that Century 21's franchises be made available to anyone with a real estate license. The Commission considered the "Realtor only" provision to be discriminatory.
15. 415 F. Supp. 1258 (N.D. Fla. 1976), aff'd in part, rev'd in part, rem., 586 F. 2nd 530 (5th Cir. 1978).
16. Pontius v. Children's Hospital, 552 F. Supp. 1352 (W.D. Pa. 1982).
17. Id. at 1369-70.
18. Weiss v. York Hospital, supra, at 66,70.
19. Id.
20. Id. at 71.
21. Indiana Federation of Dentists v. FTC, 1984-2 Trade Cases (CCH) Par. 66,229 (7th Cir. 1984).
22. 593 F. Supp. 607 (D. Nev. 1984).
23. Id. at 610; whether they are applied neutrally or not was not before the court as it was in Weiss v. York Hospital, supra.
24. Id.
25. Id. at 611 n. 13.
26. 16 Cal. 3d 920, 549 P.2d 833, 130 Cal. Rptr. 1 (1976).
27. T. Muris and F. McChesney, "Advertising and the Price and Quality of Legal Services: The Case For Legal Clinics," 1979 American Bar Research Foundation Journal, pp. 179-207.
28. The authors used t-tests and stepwise multiple regression analysis in determining whether there were statistically significant differences between the two classes of law service providers in terms of selected quantifiable performance measures. An in-depth description of the statistical methodology and treatment employed is beyond the scope of this article, readers are referred instead to Muris and McChesney, id., or W. Trombetta, "Competition in the Professions: Good or Bad?" Business (May-June 1981).
29. Despite the "public service and ethical norms" language accompanying three Supreme Court opinions that involved price fixing, the medical profession would still be well advised to avoid absolutely and entirely even the remotest semblance of any combined tampering with prices.

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Saccharin

Review of Safety Issues

AMA COUNCIL ON SCIENTIFIC AFFAIRS

This report reviews the experimental and epidemiologic data related to the carcinogenicity of saccharin. The results of animal studies suggest a species and organ effect. In single-generation studies in rats, mice, hamsters, and monkeys, saccharin did not induce cancer in any organ. In two-generation studies involving rats, however, there was evidence that the incidence of bladder tumors was significantly greater in saccharin-treated males of the second generation than in controls; the development of bladder tumors in rats seems to be a species- and organ-specific phenomenon for which there is currently no explanation. In humans, available evidence indicates that the use of artificial sweeteners, including saccharin, is not associated with an increased risk of bladder cancer. Until there is firm evidence of its carcinogenicity in humans, saccharin should continue to be available as a food additive, and reports of adverse health effects associated with its use should be monitored.

In its report "Saccharin Availability," adopted at the 1979 Interim Meeting of the House of Delegates of the American Medical Association (AMA), the Council on Scientific Affairs recommended that:

> The AMA continue to support extension of the present moratorium on the ban of saccharin and support efforts to keep saccharin available as a food additive and table-top sweetener until (1) stronger evidence of its carcinogenicity is forthcoming, or (2) an alternative nutritive or non-nutritive sweetener becomes approved.

Reconsideration of this recommendation is now in order for two reasons: the moratorium on the ban of saccharin has been extended until April 1985, and reports of new studies on the safety of saccharin are now available. In addition, a new nutritive sweetener, aspartame, has been approved for use in foods [1] and carbonated beverages. [2] This report describes the background of the regulation of saccharin and summarizes the most recent research findings concerning the safety of this food additive.

Saccharin

The nonnutritive sweetener, saccharin, is 300 times sweeter than sucrose. It is absorbed slowly, is not metabolized, and is excreted rapidly, unchanged by the kidneys. Because of its functional properties and its stable shelf life, saccharin has been used in soft drinks, table-top sweeteners, and a wide variety of other foods and beverages. [3, 4]

In 1977, the Food and Drug Administration proposed to prohibit the use of saccharin on the basis of a study conducted by the Canadian Health Protection Branch, [5] which reported that bladder tumors were found in second-generation male rats. In response to the public outcry over

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From the Council on Scientific Affairs, Division of Drugs and Technology, American Medical Association, Chicago

This report was adopted as amended by the House of Delegates of the American Medical Association at the Annual Meeting, June 1985.

This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. This report reflects the views of scientific literature as of 1984.

Reprint requests to Council on Scientific Affairs, Division of Drugs and Technology, American Medical Association, 535 N Dearborn St, Chicago, IL 60610 (John C. Ballin, PhD).

Members of the Council on Scientific Affairs include the following: John R. Beljan, M.D., Philadelphia; George M. Bohigian, M.D., St. Louis; William D. Dolan, M.D., Arlington, Va.; E. Harvey Estes, Jr., M.D., Durham, N.C.; Ira R. Friedlander, M.D., Chicago, Resident Physician; Ray W. Gifford, Jr., M.D., Cleveland, Chairman; John H. Moxley, III, M.D., Beverly Hills, Calif., Vice-Chairman; Peter H. Sayre, Boston, Medical Student; William C. Scott, M.D., Tucson; Joseph H. Skom, M.D., Chicago; Rogers J. Smith, M.D., Portland, Ore.; James B. Snow, Jr., M.D., Philadelphia; John C. Ballin, Ph.D., Secretary; Diane Morris, Ph.D., Staff Author.

this proposed action, the US Congress declared a moratorium on the ban until additional research on saccharin's safety could be conducted. In April 1983, President Reagan signed into law a bill extending the saccharin-ban moratorium until April 22, 1985.

Since the report of an association between saccharin and bladder cancer in male rats,[5] many studies of saccharin's biologic effects have been completed. Two questions related to saccharin safety have been posed: (1) Is saccharin itself carcinogenic, or do impurities in commercial saccharin contribute to tumor development? (2) Is there epidemiologic evidence that exposure to saccharin is associated with increased cancer morbidity in humans?

Experimental Data

Impurities.—Because impurities may contribute to the toxicity of a test compound, Riggin and Kinzer[6] examined the organic-extractable impurities in commercial lots of sodium saccharin produced by the Sherwin-Williams process, which is the only commercial synthetic process used to produce saccharin in the United States. Of the impurities identified, no single compound exceeded 1 ppm, and most of the contaminants were derived from the polyethylene storage bags. In a related study,[7] the mutagenic activity of impurities extracted from samples of commercial saccharin was tested. None of the compounds identified were mutagenic, although several organic extracts of certain saccharin samples exhibited low-level mutagenic activity. In addition, there is no evidence that the major contaminant of saccharin, *o*-toluenesulfonamide, causes cancer in rats.[8] Given the low level of mutagenic activity observed and the large amount of organic extracts required to produce a significant mutagenic response, the saccharin contaminants seem to be of little toxicologic significance in animal-feeding studies.[7]

Carcinogenicity.—In its review of 14 lifetime-feeding studies to determine saccharin toxicity, the Committee for a Study on Saccharin and Food Safety Policy of the National Academy of Sciences (NAS)[8] concluded that in the single-generation studies involving rats, mice, hamsters, and monkeys, saccharin did not induce cancer in any organ. In two-generation studies involving rats exposed to saccharin in utero, during lactation, and after weaning, there was evidence that bladder tumor incidence was significantly greater in saccharin-treated males of the second generation than in controls. Since the NAS review, numerous studies have confirmed that saccharin promotes tumors and is a low-potency bladder carcinogen in the male rat.[9-12]

Recently, an expert panel[13] was convened to review published and unpublished data on saccharin, including data from a rat study conducted at the International Research and Development Corporation (IRDC). The IRDC study was designed to determine the dose response for urinary bladder tumors in saccharin-treated rats, to evaluate other physiological or pathological changes that may be related to bladder tumor formation, and to evaluate the role of in utero exposure to saccharin in the occurrence of urinary bladder tumors. The panel reported that large doses of saccharin produced significant physiological changes in rat bladder tissue, including increased urine volume, increased weight of the bladder wall, and increased accumulation of divalent cations such as magnesium, zinc, and calcium in bladder tissue. Saccharin also produced a dose-related increase in the daily urinary excretion of indican, the main metabolite of indole. The exact mechanism by which these saccharin-induced changes in bladder tissue contribute to the formation of bladder tumors is unknown. In addition, these physiological changes have not been shown to occur in humans under normal patterns of use. The findings from the IRDC study indicated a clear dose response for urinary bladder tumors, with the 1% dose level considered the no-effect level. Although in utero exposure did not contribute to excess bladder pathology in the IRDC study, it seemed that the male rat was most sensitive to the effects of saccharin during the first six to eight weeks of life. Thus, the panel concluded that the development of tumors in rats seems to be a species- and organ-specific phenomenon for which there is currently no explanation.

Epidemiologic Data

A 1977 study[14] revealed that men who used artificial sweeteners (saccharin and cyclamate) had a statistically significant increase in the risk of bladder cancer, and the evidence indicated that there was a dose-response relationship. A later study,[15] however, showed no relationship between saccharin and cyclamate intake and human urinary bladder cancer.

To help characterize the relationship between use of an artificial sweetener and human bladder cancer, several epidemiologic studies were undertaken. The largest study was conducted by the National Cancer Institute (NCI) and involved approximately 9,000 persons.[16] The preliminary results indicated that, in the total study group, the use of artifical sweeteners was not associated with an increased risk of bladder cancer in either sex. Such an association was seen in two population subgroups, however—white males who smoked cigarettes heavily ($<$40/day) and nonsmoking white females who had no known exposure to bladder carcinogens.

Because the NCI study raised the possibility of an increased risk for bladder cancer in certain groups, an independent evaluation of the data was undertaken by The Epidemiology Resources Inc, Working Group on Saccharin.[17] The Working Group concluded that there was no evidence for an association between bladder cancer and use of nonnutritive sweetener in the general study group. The analysis of the study subgroups showed that "the putative effects of nonnutritive sweeteners were not consistent among subgroups with similar baseline risk, did not display consistent dose-response trends and were subject to considerable sampling error."[17]

Other studies have confirmed that the use of nonnutritive sweeteners is not associated with an increased risk of bladder cancer. In a case-control study of cancer of the lower urinary tract in the Boston area, Morrison and Buring[18] reported that, as a group, users of artificial sweeteners had little or no excess risk of cancer of the lower urinary tract. In a later case-control study in Manchester, the United Kingdom, and Nagoya, Japan, Morrison et al[19] reported that the use of artificial sweeteners was not associated with increased risk of bladder cancer. In a study of the Danish population born during World War II,[20] there was no evidence that exposure to saccharin in utero was associated with an increased risk of human bladder cancer during the first 30 to 35 years of life. Moller-Jensen et al[21] concluded in a study of bladder cancer risk in Copenhagen that neither saccharin nor cyclamate users had an increased risk of bladder cancer. Another case-control study of bladder cancer in New Jersey[22] found no "association between regular consumption of saccharin at moderate dietary levels and bladder cancer."

These[23] and earlier[8] epidemiologic studies have been criticized because of methodological difficulties, including the lack of sensitivity for detecting the effects of relatively weak carcinogens; the presence of confounding factors, such as cigarette use and exposure to occupational carcinogens; the use of small sample sizes; and the inability to select appropriate cases and matched controls, to determine the amount, frequency, and duration of saccharin exposure, and to separate the effects of saccharin and cyclamate. Despite these limitations, recent epidemiologic studies provide no evidence of increased risk of bladder cancer to users of artificial sweeteners, including saccharin.[16] Little or no data exist, however, for the effects of saccharin on young children and pregnant women, two subgroups about which special concern has been indicated.[8] Hence, consumption patterns and reports of adverse health effects associated with the use of saccharin should continue to be monitored and evaluated.

Comment

The ideal alternative sweetener should be sweeter than sucrose, with a pleasant taste and no bitter aftertaste; chemically and physically stable, colorless, odorless, and water-soluble; suitable for a variety of applications in food and beverage products; competitive in cost; and free of adverse health effects.[24] No single alternative sweetener has all of these characteristics. For example, while saccharin is stable at a wide range of temperatures in both dry and liquid formulations, it has a slight bitter aftertaste; aspartame, on the other hand, has a pleasant sweet taste but loses sweetness when exposed to prolonged high temperatures.[4] Therefore, the use of a variety of sweeteners affords the greatest range of applications. In addition, the use of multiple sweeteners in combination can reduce the consumption of any single sweetener.

Saccharin is the oldest nonnutritive alternative sweetener in the US food supply and is used in a wide variety of foods and beverages, cosmetic and toiletry products, tobacco, and drugs.[23] Perceived benefits of saccharin use include maintenance of desirable body weight, facilitation of weight reduction, prevention of dental caries, control of diabetes, and promotion of proper use of prescribed drugs.[8] In evaluating the benefits of saccharin, the NAS Committee for a Study on Saccharin and Food Safety Policy found no studies that permitted an objective assessment of the asserted health benefits of saccharin use. The Committee recognized, however, the psychological benefit of saccharin use and concluded that "for many humans the desire for sweet taste is a demonstrable biological phenomenon and that a large segment of the population perceives sweetness without calories (for control of weight and other conditions) as a benefit."[8]

Saccharin has been identified as a low-potency carcinogen and tumor promoter in male rats.[8-13] While evidence of its carcinogenicity in laboratory animals is suggestive of a potential risk to humans, it is not possible to estimate with any confidence the magnitude of this risk.[8] Because recent epidemiologic studies provide no evidence of increased risk of bladder cancer among users of artificial sweeteners, including saccharin, and because there is no ideal alternative sweetener,[25] saccharin should continue to be available as a food additive.

Recommendations

The Council on Scientific Affairs recommends that the AMA support:

- The moratorium on the saccharin ban, since the evidence of its carcinogenicity in humans has not been forthcoming; however, the AMA is not implying that it condones the use of saccharin.
- Careful consideration of saccharin use by young children and pregnant women.
- The continued monitoring and evaluation of consumption patterns and reports of adverse health effects associated with the consumption of saccharin.
- The continued development and evaluation of both nonnutritive and nutritive sweeteners for use either singly or in combination with other sweeteners as alternatives to the natural sugars.

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Recommendations for Assisting in the Prevention of Perinatal Transmission of HTLV-III/LAV and Acquired Immunodeficiency Syndrome

CENTERS FOR DISEASE CONTROL

The information and recommendations in this document are intended to assist health care providers and state and local health departments in developing procedures to prevent perinatal transmission of human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), the virus that causes acquired immunodeficiency syndrome (AIDS).

This document contains recommendations for providing counseling and, when indicated, testing for antibody to HTLV-III/LAV for women who are at increased risk of acquiring the virus and who are either pregnant or may become pregnant. It is important that these women know they are at risk, as well as know and understand their HTLV-III/LAV-antibody status, so they can make informed decisions to help prevent perinatally acquired HTLV-III/LAV.

Through counseling, uninfected women can learn how to avoid becoming infected, and infected women can choose to delay pregnancy until more is known about perinatal transmission of the virus. If already pregnant, infected women can be provided with information for managing the pregnancy and caring for the child.

Currently available data indicate that most pediatric HTLV-III/LAV infections and AIDS cases are acquired perinatally from infected women, but additional studies are needed to better quantify the risk of transmission from an infected pregnant woman to the fetus or newborn.

The recommendations that follow pertain to women. However, men who are HTLV-III/LAV-antibody positive should also be counseled regarding the risks of sexual and perinatal transmission, so they can refer their sex partners who may be pregnant or considering pregnancy for counseling and testing.

Background

Pediatric Cases of AIDS due to Perinatal Transmission.—As of Dec 1, 1985, 217 (1%) of the 15,172 AIDS cases reported to the CDC occurred among children younger than 13 years of age. Sixty percent of these children are known to have died. These 217 cases represent only the more severe manifestations of HTLV-III/LAV infection. Less severe manifestations, often described as AIDS-related complex (ARC), are not reported to the CDC, so the number of children with clinically significant illness attributable to HTLV-III/LAV infection is greater than the reported cases of pediatric AIDS. In addition, a number of infected children are probably asymptomatic.

Of the 217 reported pediatric patients with AIDS, 165 (76%) have as their only known risk factor a mother belonging to a group with increased prevalence of HTLV-III/LAV infection. An additional 18% of the pediatric cases are attributable to transfusions of blood or blood products. Risk factor information is missing or incomplete on the remaining 6%. Of the 217 children with AIDS, 48% had mothers who were intravenous (IV) drug abusers; 17% had mothers who were born in Haiti; and 10% had mothers who were sex partners of either IV drug abusers or bisexual men.

Of the patients with perinatally acquired AIDS, 45% resided in New York City, while Florida and New Jersey accounted for an additional 32%.

Mechanisms of Perinatal Transmission.—It is believed that HTLV-III/LAV is transmitted from infected women to their fetuses or offspring during pregnancy, during labor and delivery, or perhaps shortly after birth. Transmission of the virus during pregnancy or labor and delivery is demonstrated by two reported

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AIDS cases occurring in children who had no contact with their infected mothers after birth. One was delivered by Cesarean section.

Transmission of the virus after birth has been implicated in one case of HTLV-III/LAV infection in a child born to a mother reported to have acquired the infection from a postpartum blood transfusion. Since she breastfed the child for six weeks, the authors suggested breastfeeding as the possible mode of transmission. Recently, HTLV-III/LAV has been isolated from the breast milk of infected women.

Risk of Perinatal Transmission from Infected Mothers.—The rate of perinatal transmission of HTLV-III/LAV from infected pregnant women is unknown; however, available data suggest a high rate. In one study of 20 infants born to infected mothers who had already delivered one infant with AIDS, 13 (65%) had serologic and/or clinical evidence of infection with HTLV-III/LAV several months after birth. Since these women were selected on the basis of having previously transmitted HTLV-III/LAV perinatally, this study may overestimate the average risk of transmission for all infected pregnant women.

Perinatal transmission from an infected mother to her newborn is not inevitable. Of three children born to women who became infected with HTLV-III/LAV by artificial insemination from an infected donor, all were in good health and negative for antibody to the virus more than one year after birth. Another child, born to a woman who was already pregnant at the time of AIDS diagnosis and was demonstrated to be viremic, was seronegative, culture negative, and healthy at birth and at 4 months of age. In a retrospective study evaluating nine children younger than 5 years of age whose mothers were later diagnosed as having AIDS, two (22%) had antibody to HTLV-III/LAV. The infection status of these women during pregnancy was unknown.

In these studies, the rate of transmission ranged from 0% (0/3) to 65% (13/20). Additional studies are needed to better define the rate of transmission and variables associated with it.

Risk of Illness Among Infected Pregnant Women.—Pregnancy is associated with suppression of cell-mediated immunity and increased susceptibility to some infections. The T-helper to T-suppressor ratio is decreased during normal pregnancy, being lowest in the third trimester, and returns to normal approximately three months postpartum. It is not known whether pregnancy increases an infected woman's risk of developing AIDS or ARC, but one study suggests it does. Fifteen infected women who were well at time of delivery were followed an average of 30 months after the births of their children. Five (33%) subsequently developed AIDS; seven (47%) developed AIDS-related conditions; and only three (20%) remained asymptomatic. These results may not apply to all infected pregnant women, but they do suggest an increased likelihood of developing disease when an HTLV-III/LAV infection occurs in association with pregnancy.

Prevalence of HTLV-III/LAV Infection.—Counseling and testing for antibody to HTLV-III/LAV, when indicated, to reduce perinatal transmission of AIDS will be most beneficial in populations of women with increased prevalence of the virus. These include women who have used drugs intravenously for nonmedical purposes; women who were born in countries where heterosexual transmission is thought to play a major role, women who have engaged in prostitution; and women who are or have been sex partners of men who abuse IV drugs, are bisexual, have hemophilia, were born in countries where heterosexual transmission is thought to play a major role, or have evidence of HTLV-III/LAV infection.

The prevalence of antibody to HTLV-III/LAV in men and women in the United States ranges from less than 0.01% in female blood donors to as high as 74% in men with hemophilia. Among heterosexual IV drug abusers, the prevalence of HTLV-III/LAV infection ranges from 2% to 59% in various geographic areas. Seroprevalence among the heterosexual partners of persons at increased risk for AIDS varies from 10% in female partners of asymptomatic, seropositive hemophilia patients to 71% in the female partners of men with AIDS or ARC. Among prostitutes, the HTLV-III/LAV antibody prevalence varies from 5% to 40%, depending on geographic area, with most of the women with positive tests relating histories of IV drug abuse. Among female blood donors in Atlanta who denied belonging to high-risk groups, 0.01% had repeatedly reactive enzyme-linked immunosorbent assays (ELISAs) followed by reactive Western blot tests.

Commercially available tests to detect antibody to HTLV-III/LAV are ELISAs using antigens derived from whole disrupted HTLV-III/LAV. When the ELISA is reactive on initial testing, it is standard procedure to repeat the test on the same specimen. Repeatedly reactive tests are highly sensitive and specific for antibody to HTLV-III/LAV. However, when the ELISA is used to screen populations in which the prevalence of infection is very low (such as blood donors or women not in high-risk groups), the proportion of repeated false-positive reactive results will be higher. For that reason, an additional test, such as a Western blot, is recommended after repeatedly reactive ELISA results, especially in low-prevalence populations. In populations with high prevalence of infection, such as homosexual men or IV drug abusers, most repeatedly reactive ELISAs are reactive by Western blot or another test. For example, among 109 IV drug abusers whose serum samples were repeatedly reactive by ELISA, more than 85% were reactive by Western blot. In contrast, in a low-prevalence population of 69 female blood donors whose serum samples were repeatedly reactive by ELISA, only 5% were reactive by Western blot.

Due to the seriousness of the implications of HTLV-III/LAV-antibody reactivity, it is recommended that repeatedly reactive ELISAs be followed by an additional test, such as the Western blot. Women with serum samples repeatedly reactive by ELISA and reactive by Western blot should have a thorough medical evaluation. HTLV-III/LAV has been isolated from a single specimen in 67% to 95% of persons with specific antibody. Because infection has been demonstrated in asymptomatic persons, the presence of specific antibody should be considered presumptive evidence of current infection and infectiousness.

Recommendations

Women Who Should be Offered Counseling and Testing.—Counseling services and testing for antibody to HTLV-III/LAV should be offered to pregnant women and women who may become pregnant in the following groups: (1) those who have evidence of HTLV-III/LAV infection; (2) those who have used drugs intravenously for nonmedical purposes; (3) those who were born in countries where heterosexual transmission is thought to play a major role, (4) those who have engaged in prostitution; (5) those who are or have been sex partners of IV drug abusers, bisexual men, men with hemophilia, men who were born in countries where heterosexual transmission is thought to play a major role, or men who otherwise have evidence of HTLV-III/LAV infection. If data become available to show that HTLV-III/LAV-antibody prevalence is increased in other groups or settings, counseling and testing programs should be extended to include them. Routine counseling and testing of women who are not included in the above-mentioned groups is not recommended due to low prevalence of infection and concern about interpretation of test results in a low-prevalence population. However if a woman requests it, the service should be provided in accordance with these recommendations.

Settings for Offering Counseling and Testing.—Counseling and testing for antibody to HTLV-III/LAV to prevent perinatal transmission is recommended in the setting of any medical service in which women at increased risk are commonly encountered. These include services for treating IV drug abuse such as detoxification and methadone maintenance, comprehensive hemophilia treatment centers, sexually transmitted disease clinics, and clinics that serve female prostitutes. In addition, services related to reproduction, such as family planning and infertility services, gynecologic, premarital, or preconceptual examinations, and prenatal and obstetric services should also consider offering counseling and testing if high-risk women are seen at these facilities. Testing for antibody to HTLV-III/LAV should be performed with the woman's consent after counseling is provided regarding risk factors for infection, the interpretation of test results, the risks of transmission, and the possible increased likelihood of disease among women infected with HTLV-III/LAV in association with pregnancy. The counseling and testing must be conducted in an environment in which confidentiality can be assured. In settings where confidential counseling and testing cannot be assured, information should be provided and referrals made to appropriate facilities.

Frequency of Testing.—Detectable antibodies to HTLV-III/LAV may not develop until two to four months after exposure. This, and whether the woman is continuously exposed, should be taken into account when considering the need for, and frequency of, repeat testing. High-risk women should be offered counseling and testing before they become pregnant. During pregnancy, counseling and testing should be offered as soon as the woman is known to be pregnant. If the initial test is negative, repeat testing may be indicated near delivery to aid in the clinical management of the pregnant woman and newborn. If this final test is negative and the mother's risk of exposure no longer exists, she may safely consider breastfeeding the child, and management of the child need not include the same concerns that would be appropriate if the woman had had a positive test or if she were at high risk and had not been tested at all.

Counseling Women with Positive Results.—Women with virologic or serologic evidence of HTLV-III/LAV infection should be counseled regarding their own risk of AIDS and the risk of perinatal and sexual transmission of HTLV-III/LAV. Infected women should be counseled to refer their sex partners for counseling and testing. If the partners of these women are not infected, both members of the couple should be counseled on how they may modify their sexual practices to reduce the risk of HTLV-III/LAV transmission to the uninfected partner. In addition, the couple should be told not to donate blood, organs, or sperm and should be discouraged from using IV drugs and advised against sharing needles and syringes. When seeking medical or dental care for intercurrent illness, they should inform those responsible for their care of their positive antibody status so appropriate evaluation can be undertaken. Recommendations for providing information and advice to individuals infected with HTLV-III/LAV have been published.

Infected women should be advised to consider delaying pregnancy until more is known about perinatal transmission of the virus. Pregnant infected women may require additional medical and social support services due to an enhanced risk of opportunistic infections and psychosocial difficulties during and after pregnancy. Obstetric care providers should be alert to signs and symptoms of HTLV-III/LAV and related opportunistic infections in these pregnant women and to the need for specialized medical care.

HTLV-III/LAV-infected women should be advised against breastfeeding to avoid postnatal transmission to a child who may not yet be infected. The child should receive follow-up pediatric evaluations to determine whether he/she has HTLV-III/LAV infection, and to diagnose and treat promptly any diseases that may be secondary to HTLV-III/LAV infection. Recommendations for educating and providing foster care for infected children have been published.

Counseling Women with Negative Test Results.—A negative ELISA for HTLV-III/LAV antibody in women who have no clinical or laboratory evidence of HTLV-III/LAV infection is evidence that they have probably not been infected. However, uninfected women who have sex partners with evidence of HTLV-III/LAV infection or with an increased risk of becoming infected should be informed that sexual intercourse increases their risk of infection. These women should be informed of the risks associated with pregnancy if they become infected and advised to consider delaying pregnancy until more is known about perinatal transmission of the virus or until they are no longer considered to be at risk for acquiring the virus. In addition to preventing pregnancy, the consistent and proper use of condoms can offer some protection against HTLV-III/LAV infection.

High-risk women, even if seronegative, should be told not to donate blood or organs. To decrease their risk of becoming infected, IV drug abusers should be encouraged to seek treatment for their drug abuse. If drug abuse is continued, they should be advised not to share needles or syringes and to use only sterile equipment. Persons counseling IV drug abusers should know that IV drug abuse is often strongly ingrained and compulsive. Despite educational efforts and encouragement for treatment, some addicts will continue to abuse drugs or relapse after treatment.

Additional Considerations.—These recommendations will be revised as additional information becomes available. It is recognized that provision of the recommended professional counseling, HTLV-III/LAV-antibody testing and associated specialized medical services will take time to implement and may stress available resources, particularly in public facilities, which are most greatly affected. Health care providers, social service personnel, and others involved in educating and caring for HTLV-III/LAV-infected persons should be aware of the potential for social isolation and should be sensitive to the need for confidentiality. They should be familiar with federal and state laws, regulations, and policies that protect the confidentiality of clinical data and test results. Each institution should assure that specific mechanisms are in place to protect the confidentiality of all records and to prevent the misuse of information. Anonymous testing would not be appropriate if it prevents adequate counseling and medical follow-up evaluation.

Hospital precautions for managing infected women and infants should be patterned after those caring for patients with HTLV-III/LAV infection. Additional recommendations will follow.

Development of These Recommendations

The information and recommendations contained in this document were developed and compiled by the CDC and the US Public Health Service in consultation with persons representing the Conference of State and Territorial Epidemiologists, the Association of State and Territorial Health Officials, the American Public Health Association, the United States Conference of Local Health Officers, the American Medical Association, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the Planned Parenthood Federation of America, the American Venereal Disease Association, the Division of Maternal and Child Health of the Health Resources and Services Administration, the National Institute on Drug Abuse of the Alcohol, Drug Abuse, and Mental Health Administration, the National Hemophilia Foundation, the Haitian Medical Association, the American Bar Foundation, and the Kennedy Institute of Ethnics at Georgetown University. The consultants also included representatives of the departments of health of the areas with the largest number of perinatally transmitted pediatric AIDS cases: New York City, Florida, and New Jersey. These recommendations may not reflect the views of all individual consultants or the organizations they represented.

Current Medicolegal Issues

AMA—THE CITATION

Law That Freezes Amounts Charged By Physicians To Medicare Patients Not Unconstitutional, Court Rules

Sections of the Deficit Reduction Act freezing amounts that could be charged by physicians to Medicare beneficiaries were not unconstitutional, a federal trial court in Indiana ruled.

Several physicians, patients, the Indiana State Medical Association, and the American Medical Association brought an action challenging the constitutionality of sections of the Deficit Reduction Act. One provision of the Act froze both the prevailing and the customary charge levels for the 15-month period beginning July 1, 1984. Physicians were not permitted to charge at levels higher than the levels set for the 12-month period prior to July 1, 1984. Non-participating physicians were limited to charging Medicare patients no more than their actual charges for the calendar quarter beginning on April 1, 1984.

In addition, the Act provided that participating physicians had to accept all Medicare payments by assignment of benefits. Prior to the Act, a physician could either accept assignment of benefits or could charge the patient directly. If the physician chose not to accept assignment, there was no limitation on the amount he could charge a Medicare beneficiary. Under either situation, Medicare would normally pay 80 per cent of the reasonable charge, and the Medicare patient would be liable for the balance.

The Act encouraged physicians to become participating physicians by mandating that the Secretary of Health and Human Services publish a directory of participating physicians to be made available to all Medicare beneficiaries and to provide for the electronic receipt of claims from participating physicians enabling them to have their claims processed more quickly.

In a five-count complaint, the physicians and the AMA claimed that the freeze on the amount that non-participating physicians may charge their patients discriminated against them in an arbitrary and irrational fashion in violation of the equal protection provision. The second count claimed that patients would be unable to obtain medically necessary services and treatments from the physicians of their choice, thereby depriving them of their rights of privacy, personal liberty, equal protection, due process, and protection against arbitrary and capricious governmental action. In count three, the Medicare beneficiaries claimed that the government breached its contractual promise that they would be entitled to freely choose among qualified physicians and that they would receive equivalently-calculated reimbursements for physicians' services regardless of their choice.

In count four, certain physicians and the two medical associations claimed that the failure to release information essential to physicians' decisions on whether to become participating physicians caused the October 1, 1984, deadline to be fundamentally unfair and in violation of the Due Process Clause of the Fifth Amendment. Finally, in count five, the physicians and medical associations asserted that a letter defining the phrase "actual charges for the calendar quarter beginning on April 1, 1984" violated the requirements of the Administrative Procedure Act because no prior public notice and opportunity for comment was given.

Dismissing the claims in counts two and three that as a result of the fee freeze, Medicare patients will be unable to obtain medical services from the physicians of their choice, the federal trial court said that there was no evidence that any of the patients had been denied the services of a physician of his or her choice because the patient was a Medicare patient. They failed to demonstrate that anyone had denied them access to physicians of their choice. Applying the rational relationship test to the other three counts, the trial court said that the fee freeze was rationally related to Congress's reasonable objective of controlling the federal deficit and Medicare costs.

The "Dear Dr." letter sent by the Secretary to physicians defining the phrase "actual charges for the calendar quarter beginning April 1, 1984" was not a rule or regulation that was subject to the notice and comment provisions of the Administrative Procedure Act. The letter, which interpreted the meaning of the

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term "actual charges" as used by Congress in the Deficit Reduction Act, may not be the only fair or desirable interpretation of the statute, the court said. However, it was sufficiently reasonable to conform with both the plain language and intent of the act.

The court entered judgment in favor of the government on the claims based on equal protection and violation of the Administrative Procedure Act.—*American Medical Association v. Heckler,* 606 F.Supp. 1422 (D.C., Ind., April 18, 1985)

$412,000 Awarded In Malpractice Suit For Pain And Suffering

An award of $412,000 for pain and suffering caused by medical malpractice was supported by substantial evidence, the Washington Supreme Court ruled.

The patient, a 26-year-old woman, died in a hospital on the second day after childbirth. Her death was caused by the progression of undiagnosed preeclampsia to eclampsia and disseminated intravascular coagulation, resulting in uncontrolled bleeding into her brain. The physician who followed her during pregnancy but failed to perform appropriate tests later admitted that her life could have been saved with proper treatment.

The evidence showed that the patient died approximately 30 hours after she first complained of pain on the evening after the delivery. Her hospital roommate testified that she appeared to be in extreme pain and thought she was dying, calling for help. She suffered three grand mal seizures early the next morning. She told a nurse that she felt awful, was nauseated, had a headache, and hurt all over her body. She was transported to another hospital, where she arrived in an unresponsive, "stuporous" condition, and died that night. During some of this time, she was not conscious because of medication or her physical condition.

The patient's husband brought a wrongful death and survival action against the hospital and her physician. An award of $1,002,089 was affirmed on appeal, with the exception of a $412,000 portion for pain and suffering.

On review, the Washington Supreme Court said that other than the amount of the verdict, the record showed nothing to suggest that the jury was prejudiced against the hospital and physician or that it was incited to passion and prejudice. The court said that the facts with regard to the patient's pain and suffering were sufficiently impressive that the award was not shocking.

The patient's death was caused by malpractice, and she left a surviving spouse and children. Further, the jury was entitled to consider the patient's fear that she was dying. Reversing the reduction of the amount of damages, the court reinstated the judgment of the trial court.—*Bingaman v. Grays Harbor Community Hospital,* 699 P.2nd 1230 (Wash. Sup.Ct., May 23, 1985)

Hospital Negligent In Treating Patient's Leg Infection

A patient and his wife were properly awarded $200,000 for injuries caused by a hospital's failure to administer a proper antibiotic, a New York appellate court ruled.

The patient, a 42-year-old dairy farmer, was injured in an accident on September 23, 1977. A tree limb punctured the groin area of his right leg and knocked him off his tractor. He was taken to the hospital, where he was given penicillin, a tetanus injection, Demerol, and Cefadyl. Also, a culture was taken. The patient was later taken to the operating room, and the wound was cleaned, debrided, and partially closed by a surgical resident.

A pathology report received the next day established that the wound was already infected at the time of the procedure. Three days later, the culture sensitivity test showed that the bacteria present in the wound were sensitive to at least ten different antibiotics. The bacteria was not sensitive to penicillin. However, none of the ten antibiotics was administered to the patient until October 21, 1977. A skin graft performed on September 28th was unsuccessful because the wound was heavily infected. Two later grafts were also unsuccessful.

As a result, the patient suffered a permanent disability to his right leg, which limited his ability to perform farm chores. He had to employ additional farm laborers, and his wife had to perform additional chores. A trial court awarded him $150,000 and his wife $50,000.

Affirming the decision, the court said that expert medical testimony showed that the treating physicians deviated from accepted medical standards in treating the patient. The expert testified that a plastic surgeon should have been consulted, and that administration of proper antibiotics would have increased the chances of a successful skin graft, shortened the patient's hospital stay, and probably lessened any disability.

The court said the finding of malpractice was proper, and the amount of the verdict was not excessive.—*O'Connell v. Albany Medical Center Hospital,* 475 N.Y.S.2nd 543 (N.Y.Sup.Ct., App.Div., April 12, 1984)

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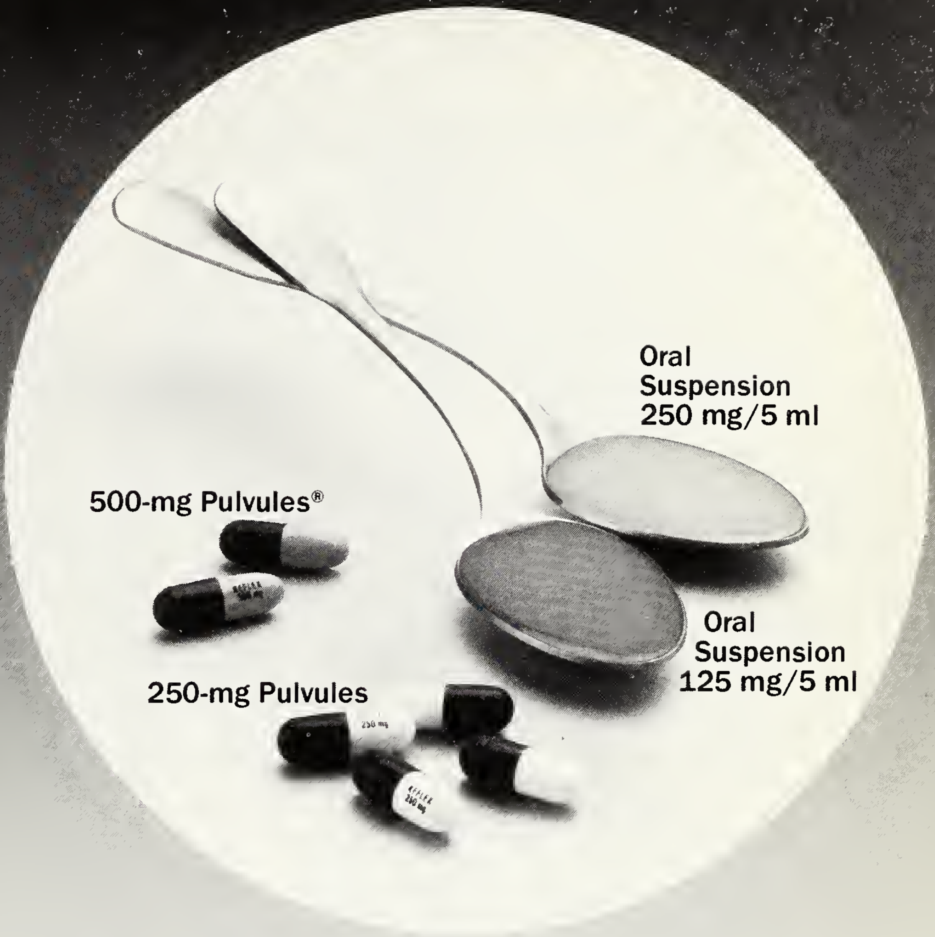

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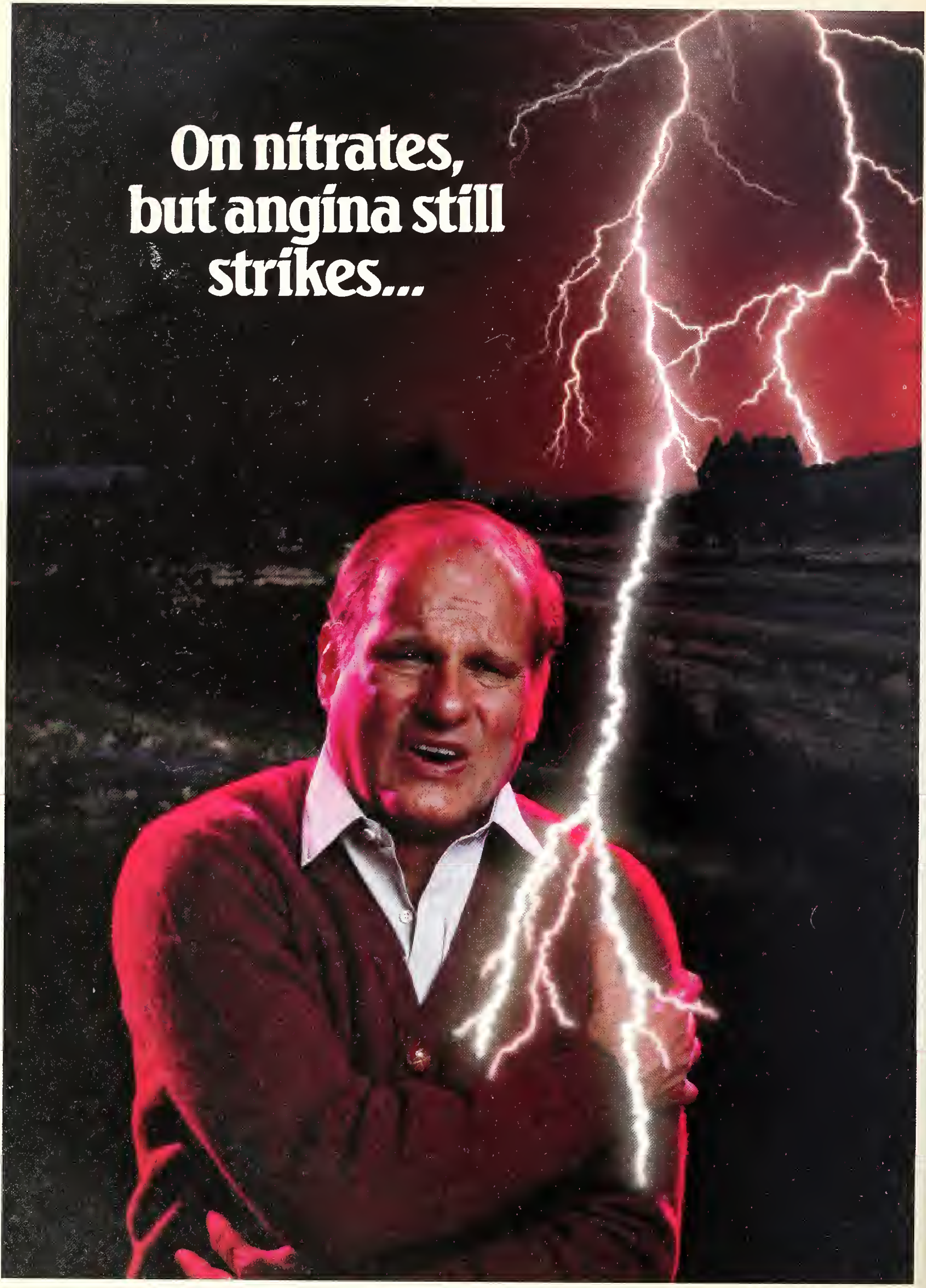
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Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Such elevations may disappear even with continued treatment; however, four cases of hepatocellular injury by verapamil have been proven by rechallenge. Periodic monitoring of liver function is prudent during verapamil therapy. Patients with atrial flutter or fibrillation and an accessory AV pathway (e.g. W-P-W or L-G-L syndromes) may develop increased antegrade conduction across the aberrant pathway bypassing the AV node, producing a very rapid ventricular response after receiving ISOPTIN (or digitalis). Treatment is usually D.C.-cardioversion, which has been used safely and effectively after ISOPTIN. Because of verapamil's effect on AV conduction and the SA node, 1° AV block and transient bradycardia may occur. High grade block, however, has been infrequently observed. Marked 1° or progressive 2° or 3° AV block requires a dosage reduction or, rarely, discontinuation and institution of appropriate therapy depending upon the clinical situation. Patients with hypertrophic cardiomyopathy (IHSS) received verapamil in doses up to 720 mg/day. It must be appreciated that this group of patients had a serious disease with a high mortality rate and that most were refractory or intolerant to propranolol. A variety of serious adverse effects were seen in this group of patients including sinus bradycardia, 2° AV block, sinus arrest, pulmonary edema and/or severe hypotension. Most adverse effects responded well to dose reduction and only rarely was verapamil discontinued. **Precautions:** ISOPTIN should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacologic effects. Studies in a small number of patients suggest that concomitant use of ISOPTIN and beta blockers may be beneficial in patients with chronic stable angina. Combined therapy can also have adverse effects on cardiac function. Therefore, until further studies are completed, ISOPTIN should be used alone, if possible. If combined therapy is used, close surveillance of vital signs and clinical status should be carried out. Combined therapy with ISOPTIN and propranolol should usually be avoided in patients with AV conduction abnormalities and/or depressed left ventricular function. Chronic ISOPTIN treatment increases serum digoxin levels by 50% to 70% during the first week of therapy, which can result in digitalis toxicity. The digoxin dose should be reduced when ISOPTIN is given, and the patients should be carefully monitored to avoid over- or under-digitalization. ISOPTIN may have an additive effect on lowering blood pressure in patients receiving oral antihypertensive agents. Disopyramide should not be given within 48 hours before or 24 hours after ISOPTIN administration. Until further data are obtained, combined ISOPTIN and quinidine therapy in patients with hypertrophic cardiomyopathy should probably be avoided, since significant hypotension may result. Clinical experience with the concomitant use of ISOPTIN and short- and long-acting nitrates suggest beneficial interaction without undesirable drug interactions. Adequate animal carcinogenicity studies have not been performed. One study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. *Pregnancy Category C:* There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor and delivery only if clearly needed. It is not known whether verapamil is excreted in breast milk; therefore, nursing should be discontinued during ISOPTIN use. **Adverse Reactions:** Hypotension (2.9%), peripheral edema (1.7%), AV block: 3rd degree (0.8%), bradycardia: HR < 50/min (1.1%), CHF or pulmonary edema (0.9%), dizziness (3.6%), headache (1.8%), fatigue (1.1%), constipation (6.3%), nausea (1.6%), elevations of liver enzymes have been reported. (See *Warnings.*) The following reactions, reported in less than 0.5%, occurred under circumstances where a causal relationship is not certain: ecchymosis, bruising, gynecomastia, psychotic symptoms, confusion, paresthesia, insomnia, somnolence, equilibrium disorder, blurred vision, syncope, muscle cramp, shakiness, claudication, hair loss, macules, spotty menstruation. **How Supplied:** ISOPTIN (verapamil HCl) is supplied in round, scored, film-coated tablets containing either 80 mg or 120 mg of verapamil hydrochloride and embossed with "ISOPTIN 80" or "ISOPTIN 120" on one side and with "KNOLL" on the reverse side. Revised August, 1984. 2385

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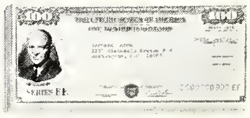

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Parents Of Dead Child Cannot Recover For Emotional Or Psychic Harm

The parents of a child who died at the age of six days could not recover for emotional and psychic harm resulting from the death, a New York appellate court ruled.

Affirming dismissal of the parents' claim, the appellate court said that there was no allegation that the parents were subjected to an unreasonable risk of bodily injury due to the alleged negligence of the hospital and physicians. The basis for liability for emotional and psychic harm was breach of duty of care owed to the parents. If the parents were negligently exposed to an unreasonable risk of bodily injury or harm, then they could also recover damages suffered from observing serious injury or death to a family member.

The parents were not in the zone of danger, and the hospital and physicians breached no duty of care towards them, the court said. Dismissal of the complaint was proper.—*Osborn v. Andrus Pavilion of St. John's Riverside Hospital,* 474 N.Y.S.2nd 76 (N.Y. Sup.Ct., App.Div., April 2, 1984)

Suit By Surgery Patient With Keloid Scar Should Not Have Been Dismissed

A patient's claim of medical malpractice based on lack of informed consent should not have been dismissed on a summary judgment motion, the Colorado Supreme Court ruled.

On February 5, 1977, a physician removed a small nodule from the back of the patient's shoulder. He obtained her consent to the surgery after explaining that she would have a scar but not a bad one. The patient was dark-skinned. Several months later she returned because the scar had become larger, unsightly, and uncomfortable. He gave her no additional treatment or explanation.

She was treated by two other physicians and discussed the scar with at least two attorneys. In August 1979, a physician at a university medical center told her that keloid had developed on her shoulder, and that young, dark-skinned persons run a high risk of getting keloids. Three months later, in November 1979, she filed a malpractice action against the physician who removed the nodule for failure to inform her of the risk of keloid formation. She did not claim that the physician was negligent in performing the surgery.

A trial court dismissed the action as barred by the two-year statute of limitations, and an appellate court reversed.

The Colorado Supreme Court affirmed the appellate court's decision. The two-year statute of limitations began to run when the patient had notice of her injury and that the injury was caused by the wrongful conduct of another, the court said.

The court said that only in the clearest of cases may a summary judgment motion be granted where discovery of the injury is the pivotal issue. Here, it is a question of fact whether, during the period from July 1977 to July 1979, the patient should have discovered that either the physician had been negligent in performing the surgery or that he had failed to advise her before surgery that a keloid scar could develop and that she was a member of a high risk class, or whether the patient discovered her injury when she visited the specialist during August 1979, when she was advised of her high risk status for keloid scarring.—*Mastro v. Brodie,* 682 P.2d 1162 (Colo.Sup.Ct., May 7, 1984, rehearing denied, May 29, 1984)

Waiting Period For Abortion Unconstitutional

A 24-hour waiting period imposed on minors under the Illinois Parental Notice Abortion Act was unconstitutional, a federal appellate court for Illinois ruled.

In a class action challenging the Act, the federal trial court found that the waiting period imposed after a minor had notified both parents of her decision to have an abortion unconstitutionally burdened the minor's right to have an abortion. The court also found that the judicial procedures permitting waiver of notice were unconstitutional because they failed to assure that the proceedings would be conducted expeditiously and confidentially. The court found that the provisions in question could not be severed from the Act and declared the entire Act unconstitutional.

On appeal, the federal appellate court agreed that the waiting period was unconstitutional, but found that the provisions of the Act relating to it might be severed without affecting the essential purpose of the Act. Vacating the lower court's holding that the Act was unconstitutional, the court enjoined enforcement pending enactment of rules assuring expeditious and confidential disposition of judicial hearings permitting a minor to forego the notice requirement. The court sent the case back for determination of the constitutionality of the waiver of notice proceedings after enactment of such rules.—*Zbaraz v. Hartigan,* 763 F.2d 1532 (C.A.7, Ill., May 20, 1985)

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194th ANNUAL MEETING
OF THE
CONNECTICUT STATE MEDICAL SOCIETY
PARK PLAZA HOTEL, NEW HAVEN
Thursday, May 8, 1986

GENERAL SCIENTIFIC PROGRAM

MORNING SESSION

8:15 REGISTRATION—Mezzanine

8:30-10:00 MEETINGS OF SECTIONS OF THE SOCIETY

10:00 INTERMISSION TO VISIT EXHIBITS

BALLROOM

10:20 CALL TO ORDER AND WELCOMING REMARKS
President, Connecticut State Medical Society

10:25 INTRODUCTIONS:

Franklin Robinson, M.D., New Haven
Presiding: Norman J. Marieb, M.D., New Haven

10:30 ENDOSCOPIC LASER THERAPY FOR GASTROINTESTINAL TUMORS

JAMES W. WOOD, M.D., GREENWICH: Assistant Clinical Professor, Gastroenterology, Yale University School of Medicine

ENDOSCOPIC LASER THERAPY FOR CONTROL OF HEMORRHAGE

NELSON A. BONHEIM, M.D., GREENWICH; Assistant Clinical Professor, Gastroenterology, Yale University School of Medicine

SYMPOSIUM ON OSTEOPOROSIS

11:10 ROBERT LANG, M.D., NEW HAVEN, Associate Professor of Medicine (Endocrinology)
Yale University School of Medicine

11:50 PAMELA S. JENSEN, M.D., NEW HAVEN; Associate Professor of Diagnostic Radiology,
Yale University School of Medicine

12:30 INTERMISSION TO VISIT EXHIBITS

1:00 LUNCHEON

AFTERNOON SESSION

Presiding: Franklin Robinson, M.D., New Haven

SYMPOSIUM ON THE MANY FACETS OF INFORMED CONSENT

2:00 GEORGE ROBINSON, M.D., NEW YORK; Professor of Surgery,
Albert Einstein College of Medicine, New York

2:20 J. MICHAEL EISNER, ESQ., NEW HAVEN: Senior Partner,
Wiggin & Dana Law Firm, New Haven

2:40 JAY KATZ, M.D., NEW HAVEN; John A. Garver Professor of Law and Psychoanalysis,
Yale Law School

3:00 PANEL DISCUSSION

3:30 INTERMISSION TO VISIT EXHIBITS

4:00 MEETINGS OF SECTION OF THE SOCIETY

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The President's Page

Hardening of the Hearteries

We are told that thirty million people in the United States do not have health insurance. The demographics of this figure must be defined and understood before the subject can be addressed. The implication is that the poor and the elderly comprise the majority of the thirty million people. On the other hand, we must remember that the figure includes uninsured who may be temporarily or permanently unemployed; it refers to the medically uninsurable and the "premium indigent" who find it financially difficult to obtain adequate health coverage. Finally, by inference, the Medicaid and Medicare population is included in this number.

In 1984, the uninsured consisted of 18.4% of individuals under the age of 65 who had no insurance for all or part of the year. At the same time, there was a high proportion of individuals under the age of 20 with no insurance—females 28%, males 17%; 23% of the self-employed individuals lacked insurance for part or all of the year. The lower the family income and the increased perception of poor health status increased the percentage of the uninsured or underinsured. Furthermore, there existed in the age group 55-64 a significant number of individuals who lacked insurance coverage being too young for Medicare and yet experienced a high frequency of major illness. When developing proposals to solve the problem of affordability and availability of health insurance, these and many other parameters must be considered.

On the other side of the thirty million dollar "coin," we are dealing with individuals in the Medicaid and Medicare population who have experienced or will continue to experience compromised medical attention because of past or future cutbacks in government programs. With the projected cuts in Medicare benefits, people over 65 will be forced to assume greater responsibility for health care payments.

In 1980-1982, cutbacks occurred in Medicaid and other government assistance programs. Services by some public hospitals were reduced. The unemployment rate increased during this period as did the number of people under the poverty level. High risk patients expressed difficulty in obtaining health care coverage. As a result, "cost shifting" occurred and third party payors were no longer willing to pay the "padded" bills to cover the expense of caring for the poor and the uninsured. Although "cost shifting" is difficult to analyze and quantify, commercial insurers stated that they had paid more for the same level of care than did Medicaid, Medicare, Blue Cross and Blue Shield who enjoyed discounts. The estimate was placed at 5.8 billion dollars in the year of 1982.

Consequently, in the spirit of resignation, the States have assumed the burden of confronting the problem of the uninsured, the underinsured, and the plight of the indigent population. More than thirty States have debated the issue, and many States have passed specific legislation: 1) Some of the States have required insurers to cover the unemployed who could afford to pay their own insurance premiums. 2) Risk sharing pools have been formed to insure cancer patients and other high risk patients. 3) Nineteen States have expanded Medicare eligibility, and thriteen have added benefits. 4) Twelve States have instituted DRG's for the reimbursement of Medicaid in-patient hospital care. 5) The significant problem of long-term care is being addressed. 6) Thirty-four States have received federal waivers permitting them to fund certain home community based social services through the Medicaid program. Less than 100,000 individuals of the 6.1 million aged, blind, and disabled have benefited from these waiver programs.

Traditionally, physicians and hospitals have responded generously with organized programs to serve the poor, the elderly, and the uninsured. Presently, a Coalition for Responsible Health Care of the poor and the elderly has been organized by the Connecticut Hospital Association in order to address the existing problems. The Connecticut State Medical Society is participating in this effort and the Statewide Medical Planning Committee is studying the problem independently.

We are a profession that deals with "pain and suffering" on a day to day basis; we do not profit "twice" from collateral source payments, and we are not reimbursed on a contingency fee basis for our service. As the Medicare body ages, and the arteries of reimbursement harden, physicians will continue to respond to the needs of their patients in spite of their ability to pay. I doubt that "Hardening of the Hearteries" will develop!

William A. Whalen, M.D.
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Reflections on Medicine

The Meanest Sayings

ROBERT U. MASSEY, M.D.

Every profession, like every family, has its ups and downs. Right now doctors are under fire, and so for that matter are lawyers and school teachers. Society seems to be reminding us all that higher standards of professional behavior are expected than we have been pleased to impose upon ourselves. There is nothing new in any of this; we can all remember unpleasant references to both physicians and lawyers in the literature of the past. Recall Chaucer's lines from the Prologue to *The Canterbury Tales*:

> "With us ther was a DOCTOUR OF PHYSYK,
> In al this world ne was ther noon him lyk
> To speke of phisik and of surgerye;
> For he was grounded in astronomye."

Chaucer's *astronomye* is what we should call astrology, and in the Middle Ages it was one of the basic sciences, so far had 14th century medicine strayed from the purity of its Hippocratic traditions. But Chaucer writes more about his *Doctour of Physyk:*

> "In sangwin and in pers he clad was al,
> Lyned with taffata and with sendal;
> And yet he was but esy of dispence;
> He kepte that he wan in pestilence.
> For gold in phisik is a cordial,
> Therfore he lovede gold in special."

Oswei Temkin, writing of the pious medieval doctor, confirms this: "Well, the Middle Ages saw through him and coined the adage: *'Dat Galenus opes'* (Galen gives riches)."[1]

Almost 300 years later there was Molière with his well-known attack on doctors and medical reasoning, *Le malade imaginaire*. Fielding Garrison wrote an essay, "The Evil Spoken of Physicians," and noted that C. L. Dana had begun a collection of "the meanest sayings" in a scrapbook, "then finding that their monotonous sameness rather bored and discouraged him, he finally discovered that the thing had already been done in the 17th century by Bernier and latterly in three volumes by Witkowski, entitled *Le mal qu'on a dit des médecins.*"[2]

You may remember in Swift's *Gulliver's Travels* the description of his hero's fourth voyage to the Country of the Houyhnhnms:

> "Here there was neither Physician to destroy my Body, nor Lawyer to ruin my Fortune;—No Lords, Fidlers, Judges or Dancing-Masters."

With the development of biology and scientific medicine, public respect for our profession grew as never before; for the first time in history, what doctors did could be counted upon to work; medicine had come to symbolize the way in which science and technology could be made to serve, as Francis Bacon had long ago hoped, "for the uses of life."

Now we seem to be in trouble again: our critics say that technology has replaced our humanity and greed is driving the system, or driving the system apart. Some are predicting that before the century is out, 90 percent of medical services will be in the hands of a dozen or so giant corporations, some of which will be investor owned, some not, but we shall hardly know the difference. That may be; social evolution, like natural selection, proceeds in ways which we only dimly understand and imperfectly control.

The organization of medicine, including the work both of physicians and hospitals, is in the midst of fundamental change. As physicians we can try, almost certainly unsuccessfully, to stop the change; or we can passively let it happen, even buy shares in it; or we can seize the opportunity to reshape medicine closer to the principles which have animated the best of the profession for 25 hundred years. If a dozen corporations are going to run things, it is our job to be certain that they manage the enterprise in keeping with the highest principles of scientific and altruistic medicine. It is not an impossible task; there are already some pretty good models around.

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Editorials

Palliative Care

> "When a person has a disease for which all known and professionally accepted ethical treatment has been used or excluded, and the disease is so far advanced and so debilitating that the expectation of an improved quality of life no longer exists, then therapy in anticipation of cure is no longer appropriate, and life support measures should not be used. Palliative care for the patient and spiritual and emotional support for the patient and the family should be provided."

When the Connecticut Hospice was conceived in 1971 one of the objects of the program was to teach the Hospice concept of care of the terminally ill patient, at all levels of health care.

The patient's family is primarily involved, especially in home care. Teaching here emphasizes not only hands-on care of the patient, but also emotional and spiritual support for the patient and all family members.

This teaching is of a very personal nature and is done by observing and working under the supervision of Hospice nurses, physicians, social workers, clergy and volunteers; in other words, by the entire Hospice care team.

Team members have traveled to many parts of the United States, Canada, and Europe, and participated in symposia, talked at hospitals, medical society meetings and to lay groups. These efforts have germinated new palliative care programs and helped establish Hospices in communities where such care was badly needed but was not at that time available.

The First National Hospice Symposium, sponsored by Connecticut Hospice held at Stratford, Connecticut in September of 1976 and the Catholic Hospital Association meeting in Washington, D.C. to discuss the "Hospice Concept and Objectives" in July of 1977 were springboards from which the Hospice concept of care was accepted and defined.

The curriculum in today's Medical Schools does not routinely include palliative care, rather, the emphasis rightly concentrates on methods of cure as the goal of therapeutics. Clinical experience may be a rude and unhappy teacher, for in spite of all known efforts, "cure" is not always possible.

We physicians have to learn how to shift gears and change our therapeutic goals and how to accept our inadequacies and how to be truthful with our patients and to share with them the fact that they are dying. It is not that "there is nothing more that can be done." Perhaps there is a lot that can be done to keep the patient comfortable and free of pain and other distressing symptoms while he is going through the dying process.

Connecticut Hospice has an ongoing teaching program at all staff levels. Part-time physicians have been working with us for over three years. In 1985 we initiated contact with two area medical schools and are offering 4th-year student clerkships. These will continue. We are now involved in funding for a Fellowship in Hospice Care and will be announcing this opportunity in the coming months. We envision that other Hospice teaching centers will follow suit. Thus palliative care for the terminally ill patient will become part of the training at all medical schools and an integral part of the accepted medical care in the country.

William S. Norton, M.D.

Consulting Physician,
The Connecticut Hospice, Inc.

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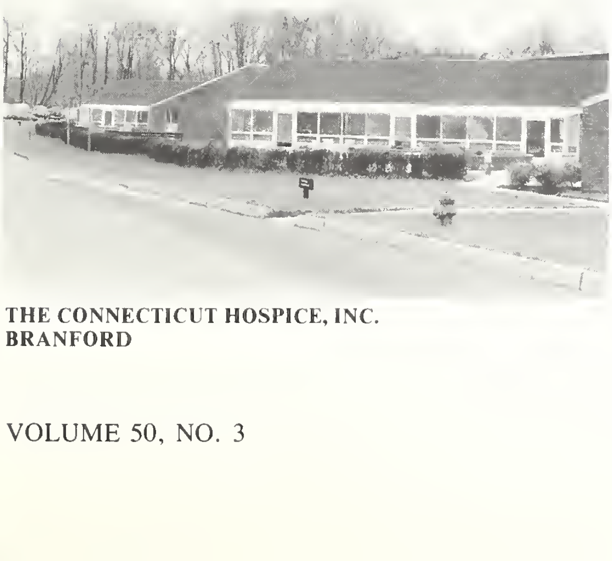
Hospice Care: A Resource for the Terminally Ill

Family practitioners, internists, oncologists, surgeons, and other physicians who have had the responsibility of caring for patients in the terminal stage of illness have long recognized the special need of these patients and their families for a type of care which has not been available in the health care delivery system. Hospice palliative care is an important resource available to the physician when radiation, surgery, and the various chemotherapy protocols are no longer effective. An understanding of the meaning of palliative care vs. agressive therapy is essential in the management of the terminally ill patient. In the pages of this issue are the criteria used at The Connecticut Hospice for identifying those individuals and the emphasis placed on agreement by the patient, family, and primary physician that palliative care is the appropriate choice.

Since many of these patients are in the older age group the diagnosis which will be ultimately responsible for death is complicated by the presence of many other chronic and acute disorders which have developed over the years. The cancer patient, a majority member of this group, in addition experiences pain and other symptoms that are unique to the diagnosis and require methods of management which are frequently not effectively utilized by physicians and other health care givers in the usual hospital or office setting. Experience gained in the Hospice setting demonstrates that appropriate use of the therapeutic tools available today in the United States—symptom control, particularly pain control, should be and can be achieved in the overwhelming majority of patients.



THE CONNECTICUT HOSPICE, INC.
BRANFORD

This special issue of *Connecticut Medicine* contains a series of papers presented by interdisciplinary team members from The Connecticut Hospice in Branford and other selected specialists in this field, during a physician symposium held as part of an interdisciplinary week of courses at a conference center in Madison in May of 1985.

The contribution from physicians, nurses, pharmacists, pastoral care, social service, arts, administration, volunteers, and dietary are all presented in this week of courses. The physician symposium emphasizes those disciplines which work most closely with the doctor at the bedside in caring for the dying patient. Daily rounds on every patient by the primary nurse, pharmacist, and physician; weekly meetings including other members of the team, provide an effective forum for the evaluation of patient/family problems and the effectiveness of therapy on an ongoing basis.

The Connecticut Hospice was the first Hospice program in the nation. Founded in 1971, after several years of study and exploration, the organization inaugurated Hospice Home Care in 1974 and opened its unique 44-bed inpatient building in Branford in 1980. The Home Care Program serves 18 towns (and cities) in greater New Haven and the building is open to patients from throughout the State of Connecticut and in some instances beyond the state lines. More than 20 other Hospice programs are located throughout Connecticut. Many offer only Home Care and an alliance between some of those and Connecticut Hospice are in the formative stage. Several inpatient units in acute care hospitals are also in existence. Connecticut Hospice in Branford encourages and assists in the development of such programs, which may serve not only as sources of referral to the inpatient facility in Branford, but also provide a focus for care for those inpatients who are able to be discharged to home throughout the State. To assist in achieving that goal, the Connecticut Hospice places great emphasis on the provision of orientation and training resources for the Hospice movement as it has developed throughout the country. Courses and seminars, technical assistance and consultation, audiovisual materials and publications are made available to help the rapidly burgeoning movement. The Connecticut Hospice Institute for Education, Training and Resource is the organizational channel for carrying out these efforts.

Robert P. Zanes, M.D.,
Guest Editor
Medical Director,
The Connecticut Hospice, Inc.

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CALL

ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1986 Annual Meeting of the House of Delegates will be held at the Park Plaza Hotel New Haven, commencing at 9:30 A.M. on Wednesday, May 7.

William A. Whalen, Jr., M.D., President
Lawrence B. Ahrens, M.D., Speaker of the House
Norman A. Zlotsky, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides:

Resolutions may be introduced by any Active or Life Member or student members or postgraduate physician members of the Society, in compliance with the following provisions:

a. *All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*

b. *Component county associations or the student members or postgraduate physician members, whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.*

c. *Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.*

d. *Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

COUNCIL MEETING

December 18, 1985

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahamed, Ahrens, Beck, Bobruff, Bonner, Canzonetti, Dardick, Freedman, Friedberg, James, Kamens, McDonnell, Orphanos, Petrie, Ragusa, Robbins, Sadowski, Scheer, Schwartz, Seide, Sullivan, Jr., Waldron, Welch, Whalen, Jr., Zanker and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Ms. Marcus, Mr. Sullivan, Mr. Tomat (FCMA), Mr. Meister (NHCMA), Mr. Coffey, (HCMA) and Ms. DeLaura (HCMA).

Absent were: Drs. Czarsty, Kaess, Reyelt, Jr., Rose, Sweet and Villa.

Reports from Physicians Serving on State and Federal Agencies

Dr. Frank Abbot reported that SHHC had adopted a plan for the state for 1986 and projected through 1990 with a long list of recommendations for medicine and the people of the State of Connecticut. In his judgment, however, very little was said on how these projects would be implemented. The staff report on CSMS monitoring of legislation and regulatory agencies was received as information.

Report of the President

Dr. William Whalen reported on the following:

Speech Seminar held on November 23, 1985: Despite competition from the Yale-Harvard game that day, there was a good attendance. County presidents have been apprised that CSMS staff would be willing to assist any county that would like to put on such a seminar. Emphasis would be on legislative activities, especially professional, and a projected speech format would be prepared for participants. The material included in these speeches would be determined in concert with the CSMS lobbyist.

Resignation from J. Alfred Fabro, M.D., Editor of Connecticut Medicine: A letter of resignation has been received from Dr. Fabro indicating that he wished to resign his post as of December 31, 1985. It was

VOTED to accept this resignation with regret and grateful thanks for the splendid job he has done and that the officers of the Society be empowered to consider ways to make proper acknowledgement to Dr. Fabro for his many years of service and bring the recommendations back to the Council. It was further VOTED that Dr. Stewart Petrie serve as temporary editor of the Journal and that the Chairman of the Council appoint an ad hoc search committee to recommend a new editor of *Connecticut Medicine.*

Voluntary Hospital Association: A survey of medical staffs of Connecticut Hospitals was undertaken and 22 replies were received. One hospital never heard of VHA, 12 were not members, of the 10 that were members, 3 were affiliates, 5 were partners and 2 were shareholders. Seven of the 10 members were asked if they had any input in the decision as to whether their hospitals should become involved with the VHA replied they had no input in the decision and that ultimately the success of the program would depend on whether or not the physicians would participate in the plan. Those who were not in the group felt that this could be potentially divisive and affect the quality of medical care and become employees of the insurance industry. The 10 hospitals that were members of the VHA replied that they were not sure how this would affect them and did not know what joining meant and hoped that there would be no deterioration of care and hospital and staff relationship.

Following a lengthy discussion, the following actions were taken:

It was VOTED to have an organization or committee established to be prepared to evaluate the third party contracts which are offered to physicians and to educate and disseminate information to the membership regarding contract evaluation and negotiations with third party payors. It was further VOTED that this committee be instructed to develop guidelines by which to evaluate third party payors contracts.

It was VOTED that the Committee on Third Party Payments be requested to study the differences in fee schedules that exist among the counties in the state and report back to the Council.

It was VOTED that the information that was disseminated by Day, Berry and Howard, legal counsel for Hartford County Medical Association, regarding the Blue Cross/Blue Shield Century 2000 contract be distributed to the physician members of CSMS and that the mailing be limited to two pages.

It was also VOTED that a summary of CSMS legal counsel's evaluation be sent to the membership at the discretion of staff.

Report of the Executive Director

Mr. Norbeck reported that to date there has been a total of 2244 responses to the defensive medicine questionnaire and that they were currently being tabulated.

He further reported that Irwin A. Schiff of Group Insurers, Inc. informed him that he has been forced to liquidate his insurance business and has transferred it to Wertheim-Eilers Association, Inc. They will have all the records so that there will be no interruption in the issuance of current policies and the handling of current claims. This information is to be communicated to the CSMS Insurance Committee.

Report of AMA Delegation

It was VOTED that CSMS report to the AMA Council on Medical Service the essence of the material that the CSMS committee has established regarding the conflict between our members and Connecticut General, as HCFA representatives, in terms of dichotomy between HCFA regulations.

It was VOTED to recommend to the Board of Trustees of the AMA that a formal presentation be made to the three magazines that do not accept tobacco advertisements.

AMA's 1985 Political Education Conference

Dr. Jerome Bobruff, Chairman of the CSMS Legislative Committee, reported on his attendance on the subject meeting in Washington, D.C. He reported that many congressmen and senators agree with the position of medicine and that physicians should get more involved in the political process. Telegrams, letter writing and an increased attendance at these AMA meetings would be effective. It was VOTED to accept the report for information.

Report of Ad Hoc Committee on Countersuits

At the October 24 meeting, final action on the subject was tabled until the December meeting of the Council. It was VOTED to take this subject off the table and accept recommendations as they appear in the October 24 Council minutes.

Resolution on Statewide IPA/HMO

In keeping with the House of Delegates' action taken on November 20, 1985, an Ad Hoc Committee has been appointed to conduct a feasibility study on the advisability of the formation of a CSMS sponsored IPA, IPA/HMO, or HMO. A proposal was distributed from Judith Mattson, Inc., Bethesda, MD, who was the consultant who worked with the Medical Association of Georgia in developing their state plan. Following a discussion and review of the activities on the subject to date, it was VOTED that the Ad Hoc Committee hold a meeting to educate the physicians on the program and to invite Council members, Presidents of the county associations and the Committee on Third Party Payments to the meeting. Ms. Mattson is to be invited to the meeting to discuss her proposal.

Labor Unions for Physicians

It was VOTED to refer to the Committee on Third Party Payments for study and report a motion submitted by George Bonner, M.D., New Haven, requesting the committee to draw up definite plans so that the Connecticut State Medical Society would be prepared to accept the challenge of acting as a negotiator in union contracts for any group of physicians that qualify as a union and ask us to represent them.

PSRO Requirements for Preadmission Certification

It was VOTED to refer to the Committee on Statewide Medical Planning a motion, submitted by George Bonner, M.D., New Haven, to study this increasing problem of added work that physicians' staffs have to do to satisfy Federal, State and Third Party Payors and to prepare a definite position that CSMS could take in regard to these growing regulations. Dr. Edward A. Kamens, Medical Director of PSRO, informed the Council that he is willing to speak to any group inviting him to discuss preadmission certification.

Communication from ACCME Committee for Review and Recognition

It was VOTED to receive as information a communication received from the subject agency commending the CSMS CME Committee and awarding the CSMS CME Accreditional Program continued recognition for a period of four years.

Life Members

Following is a list of Life Members effective 1/1/86:

Name	Town
Peter M. Dean	Greenwich
Philip D. Henry	Seymour
Frank H. Horton	Manchester
Ernest M. Izumi	Winsted
Patrick A. Izzo	Old Greenwich
Kenneth R. Kaess	Watertown

Guidelines for Exemption from Seat Belt Regulations

It was VOTED that the guidelines, as published by the New York State Department of Health, be adopted for use with Connecticut endorsement. Additional information can be obtained from the Connecticut Safety Belt Coalition, Hartford and in the January issue of *Connecticut Medicine.*

Update on Conflicting Regulation for Medicare Visits in Nursing Homes

It was VOTED to receive as information a request from the Fairfield County Medical Association's Board of Trustees that CSMS continue its attempts to clarify the conflicting regulations promulgated by the Department of Welfare Services and CIGNA. It was reported that letters had already been sent to federal legislators and the AARP making them aware of the policy of reimbursement and that a CSMS committee is currently exploring the situation with CIGNA representatives.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on December 18, 1985. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

CSMS STATEWIDE IPA–HMO UPDATE

At the autumn meeting of the Society's House of Delegates, CSMS was authorized to study the feasibility of launching a statewide physician-owned IPA-HMO (Individual Practice Association-model Health Maintenance Organization). We are charged to report the results, including a business plan, to the next CSMS House of Delegates meeting, schedules in May.

Our State is experiencing a significant increase in commercial organizations that finance health care services, including some seeking statewide coverage. These third party payors provide numerous methodologies for financing, with varying degrees of physician input and control. CSMS believes that a statewide IPA—an organization of CSMS physicians who agree to provide a defined set of medical services to people who voluntarily enroll and pay a predetermined fee—should be designed to benefit those patients and physicians, rather than commercial intermediaries. The medical society further intends to establish and control the HMO, thereby providing CSMS physicians with the ability to directly influence statewide reimbursement and financing levels, as well as the quality of patient care. Additionally, CSMS will review the development of a statewide *Managed Care System* with the physician directed IPA/HMO as its cornerstone.

The efforts of our Ad Hoc IPA/HMO committee are well under way, with weekly meetings and an action plan. The Garvey Group, a health care consulting firm located in Norwalk, Connecticut that specializes in HMO development and operations, is already at work with our committee.
The feasibility study is projected to be completed by April 15, 1986.

CSMS will keep you closely informed regarding our progress in developing a statewide IPA/HMO within the overall context of a Managed Care System, so that all member-physicians can feel satisfied and confident that it represents their concerns, interests and needs.

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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

DERMATOLOGY

The Northeast Permanente Medical Group, P.C., the Medical Group for the Hartford Connecticut area of the Kaiser Permanente Medical Care Program's Northeast Region, is seeking a board certified or eligible dermatologist in 1986. The Hartford area currently serves over 23,000 members from two ambulatory care facilities in East Hartford and Farmington. The Medical Group is a multispecialty prepaid practice organized as a professional corporation. Applicants should be willing and qualified to provide ambulatory primary care while establishing a full-time dermatology practice. Salary and benefits are highly competitive. All inquiries and resumes should be addressed to: Daniel A. Gregorie, M.D., Regional Medical Director, Northeast Permanente Medical Group, P.C., 60 Washington Street, Suite 401, Hartford, CT 06106.

INSTITUTIONAL MEDICINE

STAFF PHYSICIAN. Masonic Charity Foundation, nationally recognized as one of the finest geriatric health care providers, is currently seeking a physician to join the staff at its 650 resident multi-licensed JCAH approved Wallingford campus which includes a 150 unit continuing care retirement community. Geriatric experience preferred but will consider internists and new graduates. Will work the standard workweek, with rotation of evening and weekend call. We offer an excellent work environment, central Connecticut location, and full range of employee benefits. Salary will be commensurate with experience. Please send curriculum vitae with salary requirements to: Dr. Erlinda Rauch, Medical Director, Masonic Charity Foundation, P.O. Box 70, Wallingford, CT 06492. An Equal Opportunity Employer.

INTERNAL MEDICINE

Internist needed for Locum Tenens starting approximately April 1, 1986 at the Community Health Care Plan, Bridgeport, CT, for a period of 2 to 3 months. Hospital privileges in Bridgeport desirable. Excellent temporary opportunity. For details, contact: Ron Blumenfeld, M.D., Medical Director, Community Health Care Plan, 4000 Park Avenue, Bridgeport, CT 06604. (203) 371-1582.

Internist, BC/BE needed to join our growing HMO Network in Southwestern CT. Openings slated for March and July, 1986. If you are interested in practicing personalized, cost effective, preventive medicine with competitive salary and comprehensive fringe benefits in coastal New England, submit C.V. to: Ron Blumenfeld, M.D., Medical Director, Community Health Care Plan, 4000 Park Avenue, Bridgeport, CT 06604. (203) 371-1582.

Internist, BC/BE to join busy Internal Medicine group in Connecticut. Rapid advancement to full partnership. Send CV to CSMS, c/o IM/GD.

B/C or B/E internist sought by three physician primary care group in New Haven, Connecticut. Office well-equipped with laboratory and x-ray facilities. Initial salary with goal toward partnership. Send resume to CSMS, c/o IM/FF.

RHEUMATOLOGIST/INTERNIST. The Northeast Permanente Medical Group, P.C., the Medical Group for the Hartford Connecticut area of the Kaiser Permanente Medical Care Program's Northeast Region, is seeking a board certified or eligible Rheumatologist/General Internist for 1986. The Hartford Area currently serves over 23,000 members from ambulatory care facilities in East Hartford and Farmington. The Medical Group is a multi-specialty prepaid practice organized as a professional corporation. Applicants should have a strong interest in primary care as well as rheumatology and physical medicine. Salary and benefits are highly competitive. All inquiries and resumes should be addressed to: Daniel A. Gregorie, M.D., Regional Medical Director, Northeast Permanente Medical Group, P.C., 60 Washington Street, Suite 401, Hartford, CT 06106.

The Northeast Permanente Medical Group, P.C., the Medical Group for the Hartford, Connecticut Area of the Kaiser Permanente Medical Care Program's Northeast Region is seeking board certified or eligible internists for 1986. The Hartford area currently serves over 23,000 members from ambulatory care facilities in East Hartford and Farmington. The Medical Group is a multi-specialty prepaid practice organized as a professional corporation. Applicants should have a strong interest in primary care. For qualified candidates, there is substantial opportunity for a combined subspecialty practice. A rheumatology subspecialty is particularly desirable. Salary and benefits are highly competitive. All inquiries and resumes should be addressed to: Daniel A. Gregorie, M.D., Regional Medical Director, Northeast Permanente Medical Group, P.C., 60 Washington Street, Suite 401, Hartford, CT 06106.

MISCELLANEOUS

Immediate Medical Care Center has openings for BC/BE physicians in family practice, internal medicine or emergency medicine. Both full-time and part-time openings are available. We offer a complete benefit package as well as a competitive starting salary. If you are interested in becoming part of a high quality medical team, please forward CV to: Eugene Winchester, M.D., 850 Silas Deane Highway, Wethersfield, CT 06109.

PATHOLOGY

Wanted—Full time pathologist, AP-CP certified, for 85-bed acute care general hospital in central Connecticut growing community. Duties in general pathology with special emphasis on laboratory management and anatomic pathology. Send resumes to Vice President, Bradley Memorial Hospital, 81 Meriden Ave., Southington, CT 06489.

PEDIATRICS

Pediatric practice for sale due to retirement July 1986. Well established—Central Connecticut—Close to Hartford and New Haven. Terms negotiable. Write the CSMS Placement Serivce. c/o SALE/DD.

OPPORTUNITIES—Continued

PRIMARY CARE

Long established Primary Care Practice in very attractive community located in central Connecticut is seeking an associate to join an extremely professional and rewarding environment. Presently having two physicians. General Hospital located in community. University of Conn. Medical Center within 10 miles. No obstetrics. Partnership available. Please send CV to: CSMS, c/o PC/HH.

PSYCHIATRY

Two anticipated part-time positions for the Hartford, CT Crisis Intervention Center, a proposed, community-based, 24-hour psychiatric emergency service, operated within the State Department of Mental Health. *Both* positions are twenty hours per week with excellent benefits and flexible schedules. The program will include: ten crisis and respite beds; mobile response teams; 24-hour nursing; close affiliation with a state hospital, two community mental health centers (close proximity to one), three general hospitals and related residential and crisis telephone services. Will be working with a full-time administrative Program Director. Opportunity for extra on-call work and pay. Connecticut license required. Minority candidates are encouraged to apply. The positions are as follows: MEDICAL DIRECTOR, @ $35,000. Duties will include responsibility for clinical policies and procedures, supervision of Psychiatrist I and shift supervisors and on-call psychiatrists, management of in-service training program for mixed para and professional staff, patient services and liaison with medical community. PSYCHIATRISTS I, @ $29,500. Duties will include direct psychiatric services, staff training and clinical supervision of some staff. Call Bruce Johnson, 1-203-666-4613, ext. 266 for more information or mail CV to Personnel, Cedarcrest Regional Hospital, Russell Rd., Newington, CT 06111. AA/EOE.

PHYSICIANS WISHING TO LOCATE IN THE STATE OF CONNECTICUT

ANESTHESIOLOGY

Jan. '86. Age 47. Licensed in Connecticut. FLEX. AB elig. MD, Cairo University Medical School, Cairo, Egypt; Int. and Res., Rhode Island Medical Center and Iowa University Hospitals; Fellowship, Indiana University School of Medicine. Desires general medicine position in institutional or industrial type practice in a small to medium-sized community. Write, CSMS, c/o MG/ANES.

FAMILY PRACTICE

July '86. Age 29. Nat'l bds. AB elig. MD, University of Massachusetts, Worcester, MA; Int. and Res., Forbes Health System, Monroeville, PA. Prefers group or institutional type practice with *obstetrics* in a large coast-line community. Write, Jeffrey C. Schultz, M.D., 301 Victoria Dr., Monroeville, PA 15146.

GENERAL SURGERY

April '86. Age 65. Licensed in Connecticut. MD, NY University School of Medicine; Int. and Res., St. Vincent's Hospital, NYC. Plans to make a career shift, moving from surgery to occupational or insurance medicine. Write, Thomas F. Nolan, M.D., 504 Cherokee Dr., Erie, PA 16505.

July '86. Age 33. Nat'l bds. AB elig. MD, New York Medical College; Int. and Res., New Britain General Hospital. Prefers group, associate or institutional type practice. Write, Albert J. Torres, M.D., 33 Highland St., Apt. S-F, New Britain, CT 06050.

July '86. Age 62. Presently in practice. Licensed in Connecticut. AB cert. MD, Timicoara Medical School, Rumania; Int., Orange Memorial Hospital, Orange, NJ; Res., Middlesex General Hospital, New Brunswick, NJ. (Preceptorship, General Surgery). Desires full or part-time position in an out-patient facility. Is also looking for a practice. Write, CSMS, c/o AK/SUR.

GENERAL/VASCULAR SURGERY

July '86. Age 30. Nat'l bds. AB elig. MD, Tufts University School of Medicine; Int. and Res., St. Elizabeth's Hospital, Boston, MA. Prefers group type practice. Write, CSMS, c/o KH/SUR.

INTERNAL MEDICINE

June '86. Licensed in Connecticut. Age 30. FLEX. AB elig. MD, San Juan School of Medicine, Puerto Rico; Int., Long Island College Hospital, NY; Res., Bridgeport Hospital, Bridgeport, CT; Fellowship, University of Miami, Miami, FL. Prefers group, associate or institutional type practice in a medium-sized community. Specializes in the diagnosis and treatment of AIDS. Write, Ramon Ramirez, M.D., 8851 Fountainbleau Blvd., #304, Miami, FL 33172.

INTERNAL MEDICINE/PEDIATRICS

July '86. Age 32. Licensed in Connecticut. Nat'l bds. AB elig. MD, SUNY Downstate Medical Center; Int. and Res., Bridgeport Hospital, Bridgeport, CT. Would like to work with both specialties in a solo, group or associate type practice in a medium-sized community. Write, CSMS, MK/IM.

ORTHOPEDICS

July '86. Age 30. Nat'l bds. MD, SUNY Upstate; Int. and Res., West Virginia University Hospital. Prefers group, associate, institutional, solo and industrial type practice in this order. Write, Vito Loguidice, M.D., 1357 Headlee Ave., Unit A, Morgantown, WV 26505.

PEDIATRICS

Jan. '86. Age 28. Licensed in Connecticut. Nat'l bds. AB elig. MD, University of Puerto Rico School of Medicine; Int. and Res., University Children's Hospital, San Juan, PR. Prefers institutional type practice. Write, Maritza Viscal, M.D., 230-10 Thompson St., East Haven, CT 06513.

July '86. Age 34. Presently in practice. MD, Aleppo University Faculty of Medicine; Int. and Res., Mt. Sinai Medical Center, Case Western Reserve. Special interest in acute cases and neonatology. Prefers group or associate type practice in a medium-sized community. Write, Nikola Alain, M.D., 1667 Glenn Ave., Columbus, OH 43212.

PSYCHIATRY

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UROLOGY

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Retroperitoneal Soft Tissue Sarcomas: A Continuing Surgical Challenge

CHRISTOPHER C. BAKER, M.D. AND RICHARD J. GUSBERG, M.D.

Introduction

Retroperitoneal soft tissue sarcomas are relatively uncommon tumors and can present a major technical challenge to the surgeon. Since no one institution has a large experience with these tumors it has been difficult to delineate the appropriate forms of therapy. In an extensive review of tumors of the retroperitoneum by Felix et al,[1] seven large series of primary retroperitoneal tumors were summarized involving 627 cases. Eighty-three percent of the retroperitoneal tumors were malignant while only 27 of them were leiomyosarcomas. Recent experience with a patient who had a high grade retroperitoneal leiomyosarcoma involving the inferior vena cava prompted us to utilize the Connecticut Tumor Registry to study this subject. This study presents a case report regarding the index patient and summarizes the experience with retroperitoneal sarcomas in the Connecticut Tumor Registry from 1950 to 1980.

Materials and Methods

The records of the Connecticut Tumor Registry were accessed by computer utilizing soft tissue sarcoma and retroperitoneum as cross references. Demographic data included age, sex, and race. Clinical variables studied included history, type of tumor, therapy performed, outcome, and survival time.

Case Report

The patient was a 40 year old white female who first presented in September of 1982 with a right-sided abdominal mass. Workup at that time revealed that the mass was extrinsic to the bowel and seemed to be separate from the kidney on IVP. The patient was referred to one of the authors (CCB) who performed laparotomy in November of 1982. At this time there was a 15 × 12 × 15 cm right retroperitoneal mass overlying the kidney and extending up into Morrison's pouch. The tumor appeared to be intrinsic to the vena cava and was adjacent but not adherent to the right kidney and ureter. Two-thirds of the tumor was debulked and a hysterectomy and bilateral salpingo-oophorectomy was performed for uterine leiomyomatata. Pathology showed a retroperitoneal leiomyosarcoma grade III, and after consultation the patient was recommended for radiotherapy. Between December of 1982 and February of 1983, she received 4000 rads to the right side of the abdomen and 4500 rads to the tumor bed.

The patient tolerated radiation therapy well, but a CT scan showed no decrease in the size of the remaining tumor mass (Figure 1). Therefore, in March of 1983 a contrast study of the vena cava above and below the tumor was performed showing that the vena cava was obstructed from the iliac bifurcation to the liver with good collaterals around it (Figure 2). Therefore, both authors performed laparotomy in mid-March of 1983 with en bloc resection of the right kidney, adrenal gland, and the inferior vena cava from the liver to the bifurcation of the iliac vessels. The patient tolerated the procedure well initially but later developed a large amount of right leg edema and ascites postoperatively. In April of 1983 it became apparent that the ascites were chylous, and the ascites recurred despite several attempts at removal by paracentesis. A lymphangiogram showed a leak over the right iliac vessels, and a laparotomy with ligation of lymphatics in this area led to the patient's recovery. The patient also underwent pleurodesis with tetracycline on the right because of persistent fluid in the right chest, which resolved following this treatment.

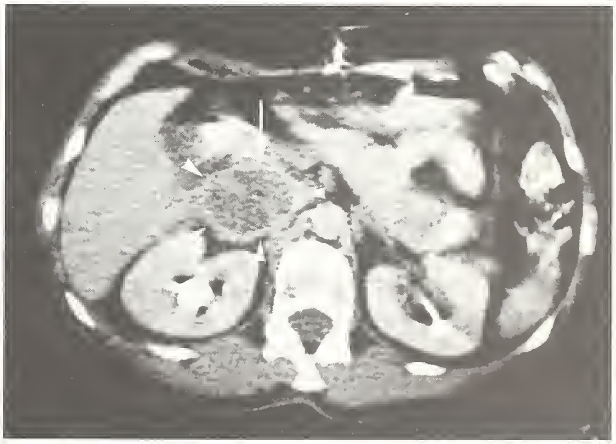

Figure 1
CT scan in February of 1982 following initial surgery and radiation therapy shows a persistent tumor mass in the right retroperitoneum (white arrows).

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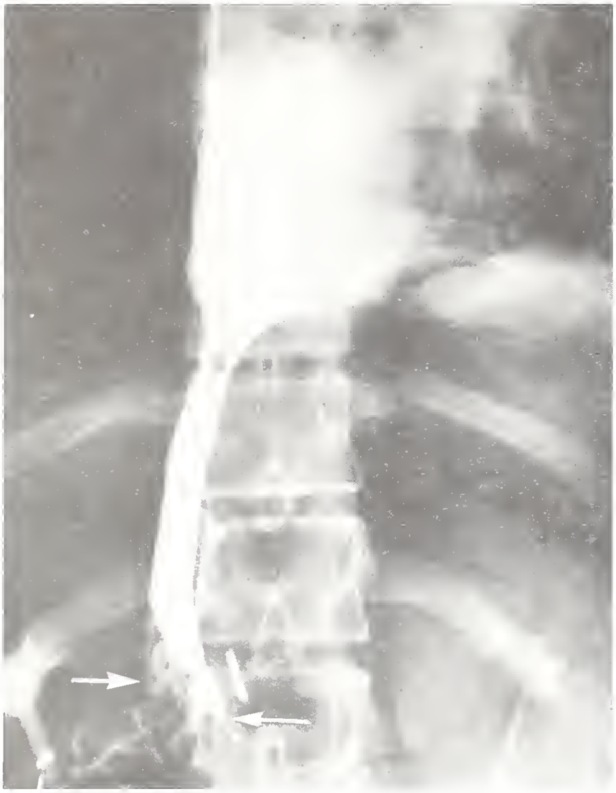

Figure 2
Inferior vena cavagram (injected from above) shows complete obstruction just below the liver (indented portion) with good collateral formation. The surgical clip marks the proximal aspect of the tumor, and the white arrows show the obstruction.

The patient returned in September of 1983 complaining of pain in the sternal area. A bone scan revealed uptake in the area of the sternum, and physical exam revealed a 5 cm subcutaneous mass in the midsternal area. An incisional biopsy was performed and was positive for metastatic sarcoma with elements similar to the primary tumor. A CT scan also suggested possible metastases in the seventh thoracic vertebra, liver, spleen, and left kidney. The patient underwent radiotherapy to the sternal area with 3000 rads, which caused regression of the mass and significant clinical improvement. The patient then underwent combination chemotherapy with adriamyein and methyl CCNU. Although she did well initially (with alopecia), 2 years later in October 1985 she developed renal failure, failure to thrive, and coma leading to her demise. The total time from initial diagnosis to death was 50 months.

This case report shows the relentless nature of high grade soft tissue sarcomas in the retroperitoneum. Nonetheless it suggests that aggressive surgical therapy can lead to substantial periods of survival and that resection of vascular structures can be accomplished in this setting. Adjuvant radiotherapy in this patient was not particularly effective in the primary tumor but was quite effective for her metastasis. Chemotherapy gave this patient a significant amount of palliation for at least a year and a half. Therefore a combined approach with aggressive attempts to remove the tumor surgically afforded this patient significant palliation.

Results

Ninety-three patients with retroperitoneal soft tissue sarcomas presenting from 1950 to 1982 were reviewed. There were 45 males and 48 females, and the majority of patients were white (89). The mean age was 54 years, but 17 patients were under the age of 10. The wide variety of histologic types is demonstrated in Table 1.

Table 1
HISTOLOGIC TYPE OF SARCOMA

Type	*Number of Patients*	*(%)*
Undifferentiated	28	(30.1)
Liposarcomas	17	(18.1)
Neuroblastoma	13	(13.8)
Leiomyosarcoma	8	(8.5)
Fibrosarcoma	8	(8.5)
Reticulosarcoma	4	(4.2)
Fibrous Histiocytoma	4	(4.2)
Myxosarcoma	3	(3.2)
Hemangiopericytoma	3	(3.2)
Mesenchymoma	3	(3.2)
Lymphosarcoma	2	(2.0)
Ganglioneuroblastoma	1	(1.0)
Total	93	(100)

Data regarding staging and original histological grade were not available from the Connecticut Tumor Registry. Treatment modalities are depicted in Table 2. As can be seen, surgery with or without radiation led to the best overall survival. Radiation alone had only a 4 percent survival, and other adjuvant methods were similar. The 11.7 percent survival with chemotherapy probably related to the fact that many of the chemotherapy patients also had surgery.

Table 2
TREATMENT MODALITIES AND OUTCOME

Therapy	*Total No.**	*No. Alive*	*(%)*
Surgery Alone	23	6	(26.0)
Radiotherapy alone	25	1	(4.0)
Surgery/Radiotherapy	24	6	(25.0)
Chemotherapy	34	4	(11.7)
Hormonal therapy	8	0	(0)
None	15	0	(0)

*Numbers are greater than 93 since some patients received adjuvant therapy.

Table 3
OUTCOME DATA

Status	*Number*	*(%)*
Alive (NED*)	10	(10.6)
Alive (? Status)	2	(2.0)
Alive with sarcoma	3	(3.2)
Dead with sarcoma	75	(81.0)
Dead (other cause)	3	(3.2)
Total	93	(100)

*NED = no evidence of disease.

Outcome data are illustrated in Table 3. At the time of this review, 75 patients (81 percent) had died due to their malignancy. The mean survival time for nonsurvivors was only 20.66 months. Of the 15 survivors, only 3 were known to have residual disease. The mean survival time in the living patients was 66.8 months (range 2 months to 24 years).

Discussion

It is apparent from the case report and review presented above that retroperitoneal sarcomas continue to be a difficult management problem. In a large recent review of soft tissue sarcomas from the National Cancer Institute, Rosenberg et al, reported on 256 sarcomas of which only 36 or 14 percent were retroperitoneal sarcomas.[2] Recurrence rates were 47 percent in the patients with retroperitoneal soft tissue sarcomas. All but one of their patients received surgery, radiotherapy, and chemotherapy. For patients who had fully resected soft tissue sarcomas in the retroperitoneum in the NCI series, the survival at nine months was 30 percent.

Probably the largest recent single series on retroperitoneal sarcomas is from Fortner's group at Memorial in New York City. They reported on 158 patients over a 26 year period with an excellent mean five year survival of 40 percent following complete excision.[3] Only 22 percent of their patients were free of disease, and five year survival after complete excision was only three percent. During the time of their study, operative mortality after incomplete excision declined from 21 percent to two percent. Anatomical barriers to wide resection, high grade histology, and local recurrence were the most important factors leading to the high mortality rate with retroperitoneal soft tissue sarcomas. The 77 percent recurrence rate in their patients who had undergone apparent complete excision emphasizes the need for adjuvant therapy such as external beam radiotherapy and chemotherapy. In more recent patients, Fortner's group has also used brachytherapy (i.e., interstitial or intracavitary delivery of radiation) with ^{125}Iodine and ^{192}Iridium.

The concept of limited surgery and brachytherapy for soft tissue sarcomas was reported in 17 patients by a group from South Africa.[4] Sixteen of the 17 patients had control of their local tumor, but it should be stated that none of these patients had retroperitoneal sarcomas. Nonetheless, this modality may have some value in treating patients in the future. Very few data exist on the role of chemotherapy in retroperitoneal sarcomas. Preliminary studies from MD Anderson Hospital employing Vincristine, Adriamycin and Cytoxan with post-operative radiation therapy have failed to show any improvement in disease-free survival with chemotherapy. Recently, however, a small uncontrolled study on the use of adjuvant chemotherapy in adult high grade soft tissue sarcomas by Mills[5] suggested a significant improvement in patients receiving adjuvant chemotherapy when compared to historical controls. The role of adjuvant chemotherapy clearly needs further study.

The specific patient reported in this paper deserves some comment. Leiomyosarcoma of the inferior vena cava is a rare and often fatal tumor. An excellent recent review compiled from Rozwell Park Memorial Institute added a case and reviewed the literature for a total of 51 cases. Only four of these 51 cases involved the entire inferior vena cava which makes our case even more unusual. They recommended extensive resection if possible with postoperative radiotherapy to prevent local recurrence. Survival in the patients in this series was anywhere from two weeks to four years. Obviously, because of the location of this tumor in the inferior vena cava pulmonary metastases are quite common. There was never any evidence of this in our patient although blood-born metastases must have occurred. Survival in our patient compares very well with survival in the series by Patell as well as with a number of other series of retroperitoneal leiomyosarcomas in which the survival rate is anywhere from 9.5 months to two years.

It becomes clear in reviewing the literature that several points must be emphasized. First, cell type and histologic grade of the sarcoma have an important bearing on ultimate outcome. Secondly, probably the most important factor affecting survival is the adequacy of surgical resection. Thirdly, even in the face of adequate resection, adjuvant therapy is recommended because the incidence of local recurrence and metastatic disease is extremely high. Finally, these tumors require an aggressive surgical approach combined with radiotherapy and possibly adjuvant chemotherapy in order to obtain good results.

Conclusion

It is clear from the case report and data presented above that retroperitoneal soft tissue sarcomas are highly malignant tumors. They often present major technical challenges to the surgeon because of the high density of important anatomic structures in the retroperitoneum. Radiation therapy alone seems to be of little value, but it may be a valuable adjuvant modality, allowing subsequent definitive excision as in the case presented here. Based on the experience presented here, we would recommend that aggressive surgical resection, including vascular structures if necessary, must form the cornerstone of the therapeutic approach to patients with soft tissue sarcomas of the retroperitoneum.

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Clinical and Serological Findings in Alloimmune Neonatal Thrombocytopenia

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ABSTRACT—In ten cases of alloimmune neonatal thrombocytopenia (ANT), the platelet count at birth averaged (±SD) 15,100±12,600/ul. The bleeding manifestations were mild and characterized by generalized petechiae in most cases. No life threatening bleeding occurred in any case. A good response to maternal platelet transfusion was obtained and post-transfusion platelet counts in the newborns averaged (±SD) 117,000±49,500/ul when measured within 12 hours of transfusion. A history of a previous sibling affected by ANT was obtained in four cases.

ABO incompatibility between the mother and the child was noted in three cases. Nine of ten maternal sera reacted against platelets. Six maternal sera also contained HLA antibodies. Three of six mothers tested were negative for the platelet specific antigen P1^{A1}.

Abbreviations

1. ANT: Alloimmune Neonatal Thrombocytopenia
2. INT: Isoimmune Neonatal Thrombocytopenia
3. ELISA: Enzyme Linked Immunospecific Assay
4. HLA: Human Leukocyte Antigens
5. NIH: National Institute of Health
6. PIFT: Platelet Immunofluorescence Test

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Introduction

Alloimmune neonatal thrombocytopenia (ANT), often also referred to as isoimmune neonatal thrombocytopenia (INT), is caused by maternal sensitization to fetal platelets during pregnancy and the subsequent transplacental transfer of maternal antibody to the fetus.[1] Newborns who develop ANT often have severe thrombocytopenia within a few hours of birth.[1] Incompatibility for the platelet antigen P1^{A1} between the mother and the child has been found in approximately half of the cases.[1] Maternal antibody, anti-P1^{A1}, in such cases is usually IgG and virtually never fixes complement.[1] In the remaining 50% of cases, the maternal antibody specificity cannot be determined because of the lack of availability of well defined anti-platelet antisera of other specificities. In this report, we describe clinical and laboratory investigation in ten cases of ANT.

Materials and Methods

Sera: Maternal sera from cases of ANT were referred to our laboratory for investigation. In all cases, the mother had a normal platelet count and she delivered a full term infant. No prenatal, perinatal or postnatal complications were present to account for thrombocytopenia in the newborn which developed within 24 hours of birth. In particular, maternal history for drug ingestion or autoimmune diseases such as lupus erythematosus or idiopathic thrombocytopenic purpura was absent. In addition, all newborns received at least one transfusion of platelets obtained from the mother. None of the newborns received platelets from random donors.

Maternal platelet collection and transfusion: Maternal platelets were collected and prepared at the transfusion services. Each facility utilized a somewhat different protocol. Of the four facilities, three used a standard plastic blood bag system to obtain platelets from whole blood collected in CPD or CPDA-1 preservative using a differential centrifugation technique. One facility used a Haemonetics Model-30 Cell Separator to prepare the platelets. In each instance, after the platelets were collected, the packed red cells were returned to the donor. No adverse reactions were reported among mothers donating platelets.

The decision to transfuse platelets to the newborns was at the discretion of the treating physicians. At the time of first transfusion, 8 of 10 newborns had a circulating platelet count of $\leqslant$ 20,000/ul. In two other newborns, the platelet counts were somewhat higher prior to transfusion (35,000/ul and 38,000/ul). In four instances, the repeat platelet transfusion was administered at even higher circulating platelet counts.

Laboratory testing: Maternal serum was tested for antibody reactive against platelets using an enzyme linked immunospecific assay (ELISA) and platelet immunofluorescence test (PIFT).[2-4] In ELISA, 31 negative control sera obtained from non-transfused male blood group AB normal donors gave an average ± SD absorbance value of 0.24±0.03. A serum was considered positive if it gave an absorbance value greater than mean + 3 SD (i.e. O.D. value $>$0.330) of negative controls. A previously described platelet immunofluorescence test (PIFT),[3] slightly modified by us,[4] was also used to detect the presence of antibody in the serum. The presence of fluorescence was subjectively evaluated as 1+ to 4+. The absence of fluorescence was considered a negative test. Maternal serum was also tested for lymphocytotoxic antibody using the standard NIH microlymphocytotoxicity test[3,5] against a panel of lymphocytes obtained from 40-60 HLA typed blood donors.

In six cases, maternal platelets were typed for Pl^{A1} antigen using ELISA and PIFT with the anti-Pl^{A1} serum.

Results

Clinical findings in 10 cases of alloimmune neonatal thrombocytopenia are presented in Table 1. Maternal platelet counts were normal in all cases. In three cases, blood group O mothers delivered either a blood group A or a blood group B baby. Two of the ABO incompatible pregnancies resulted in a positive direct antiglobulin test on cord red blood cells. Resultant neonatal hyperbilirubinemia was managed with phototherapy alone. The exchange transfusion, which could influence the platelet count, was not needed in either case. In two cases, the first born was affected. A history of a previous baby with ANT was obtained in four of the remaining eight multiparous mothers.

Pre-transfusion platelet counts which were obtained within a few hours of birth averaged (±SD) 15,100±12,600/ul (range: 4000 to 38,000/ul). Immediate post-transfusion counts (within 12 hours) averaged (±SD) 117,700±49,500/ul (range: 42,000 to 180,000/ul) (Table 2). Platelet counts were available for several days after birth in eight cases (Table 2). Repeat transfusion of maternal platelets was administered in four infants within the first week of life.

Clinical information regarding bleeding manifes-

Table 1
CLINICAL FINDINGS IN CASES OF ALLO-IMMUNE NEONATAL THROMBOCYTOPENIA

Case No.	*Maternal Age*	*Maternal Platelet count × 10^3/ul*	*Gravida*	*Para*	*Maternal blood group*	*Newborn's blood group*
1.	25	Normal	3	3	O	O
2.	26	282	3	3	O	A
3.	29	195	4	4	A	A
4.	28	181	5	4	O	B
5.	31	300	2	2	O	O
6.	38	222	4	3	O	A
7.	31	256	2	2	A	A
8.	20	Normal	1	1	A	A
9.	25	Normal	1	1	O	O
10.	NK	Normal	2	2	NK	NK

NK = Not Known

Table 2
THE SEVERITY AND DURATION OF THROMBOCYTOPENIA IN THE NEWBORNS WITH ALLOIMMUNE NEONATAL THROMBOCYTOPENIA

Case #	*Platelet count within a few hours of birth* $\times 10^3/ul$	*Platelet Count within 12 hours after transfusion of maternal platelets* $\times 10^3/ul$	*Platelet counts* $\times 10^3/ul$ *(age in days)*					
			(1)	*(2)*	*(3)*	*(4)*	*(5)*	*(6)*
1.	12	128	117	—	—	—	64↑	122
2.	20	129	112	86	68	45	28↑	171
3.	35	135	140	108	—	141	—	—
4.	4	50	34↑	136	97	75	—	—
5.	38	137	110	92	71	—	—	—
6.	12	158	218	116	174	165	—	247
7.	4	180	—	—	—	—	—	—
8.	4	50	140	170	—	230	—	370
9.	17	160	—	—	—	—	—	—
10.	5	42	17↑	274	—	232	—	—
	15.1±12.6	117.7±49.5						

↑ = Repeat platelet transfusion

tations was obtained in eight cases. This information is presented in Table 3. It should be noted that the bleeding manifestations were completely absent in three cases (Case #1, 3 and 10). In two other cases, this information was not available. In general, bleeding manifestations were mild. They were characterized by generalized petechiae, localized areas of ecchymosis or bleeding at the site of intramuscular injection. These manifestations were similar in newborns delivered by cesarian section as compared to those delivered vaginally. No intracranial hemorrhage or severe life threatening bleeding was noted in any patient.

Serological findings obtained with maternal sera from 10 cases of ANT are shown in Table 4. Using ELISA technique, five of ten maternal sera were found to react positively with platelets. Platelet reactive antibody could be demonstrated in eight of nine maternal sera with PIFT. With both techniques, the presence of platelet reactive antibody could be shown in 9 of 10 cases. Six sera were also positive for cytotoxic HLA antibodies.

Maternal platelets were typed for $P1^{A1}$ antigen in six cases. Three were found to be positive for $P1^{A1}$ antigen; the other three were negative.

Discussion

In this report, we have described the clinical and laboratory findings in ten cases of alloimmune neonatal thrombocytopenia. This condition is often referred to as isoimmune neonatal thrombocytopenia (INT). The incidence of the first born being affected by ANT that we found (30%) is lower than what has previously been reported (59%).[1] This may be due to the referral pattern or the small number of cases in this study. In three of ten cases, ABO incompatibility existed between the mother and the infant. The proportion of ABO incompatible infants in our series is not significantly different than one would expect in pregnancies in general. Maternal blood group antibody is

Table 3
BLEEDING MANIFESTATIONS IN THE NEWBORNS WITH ALLOIMMUNE NEONATAL THROMBOCYTOPENIA (ANT) IN RELATION TO THE MODE OF DELIVERY AND A PREVIOUS HISTORY OF A SIBLING AFFECTED BY ANT

Case #	*Delivery Mode*	*Previous ANT*	*Bleeding Manifestations*
1.	Cesarian	Yes	No Bleeding
2.	Cesarian	Yes	Petechiae over extremities, abdomen and face. Ecchymosis over the right lower quadrant of the abdomen.
3.	Vaginal	No	No Bleeding
4.	Vaginal	No	Petechiae over chest, face and extremities, Ecchymosis over the left side of face. Guaiac positive stools.
5.	Cesarian	No	Generalized petechiae.
6.	Cesarian	No	Hematomas over greater trochanters, thighs and at the site of vit. K injection
7.	Cesarian	No	No information
8.	Vaginal	No	No information
9.	Vaginal	Yes	Bleeding from circumcision
10.	Cesarian	Yes	No Bleeding

Table 4
SEROLOGICAL FINDINGS

Case	Maternal Serum Against Normal Donor Platelets		Maternal Serum Against Lymphocytes*	Maternal $P1^{A1}$ Phenotype	
	*ELISA***	*PIFT*		*ELISA§*	*PIFT*
1.	0.449‡	++	A11, 25, 26	0.817	++++
2.	0.474‡	++++	A2, 28	0.469	++++
3.	0.294	+	B7	1.363	++
4.	0.34‡	+	A2	NT	NT
5.	0.317	++++	B7	NT	NT
6.	Neg.	+	Neg.	0.271	Neg.
7.	0.327	+	Neg.	NT	NT
8.	0.321	+++	Neg.	0.296	Neg.
9.	0.359‡	Neg.	Neg.	NT	Neg.
10.	0.467‡	NT	48 of 50	NT	NT

* HLA antigens against which mother's serum contained the antibodies are listed. In one case (#10), the maternal HLA antibody reacted against lymphocytes of 48 of 50 donors.

** Mean ±SD O.D. value for 31 Negative Controls = 0.24 ± 0.03. Cut-off O.D. = 0.33.

§ Absorbance values are shown when maternal platelets were tested against anti-$P1^{A1}$ serum. An absorbance value $>$ 0.330 is obtained when maternal platelets are positive for the $P1^{A1}$ antigen.

‡ Positive

unlikely to be responsible for ANT in these cases although the platelets are known to express A and B antigens.[6-8] An argument against the implication of blood group antibody in ANT is the relative incidence of ABO hemolytic disease of the newborn which is much more common as compared to that of ANT.[1,9] Also, in all three cases in which ABO incompatibility existed, platelet reactive antibody was also found in mother's sera. In fact, in one case (case #6) mother's platelets were negative for $P1^{A1}$ antigen.

Even though the platelet counts were quite low in all infants, bleeding manifestations were generally mild. In a previous series of 9 cases of ANT,[10] bleeding manifestations were also generally mild in most cases. However, in 2 of 9 cases, intracranial hemorrhage was documented. Thus, therapy with platelet transfusion should be considered early whenever a diagnosis of ANT is suspected in a thrombocytopenic newborn.

A good immediate response to transfused maternal platelets was obtained in seven of our cases. In three other cases, 12 hour post-transfusion platelet counts were 50,000, 50,000 and 42,000/ul. There is no apparent explanation for this poor response to transfusion. It is possible that variable response may be due to technique of platelet preparation resulting in a variable content of platelets per unit. However, platelet content per unit of maternal platelet concentrate was not measured to examine this possibility. In two of three poor responses, a second transfusion of platelets was administered. However, in case #8, a poor responder, a spontaneous recovery of platelet count to normal was seen at one day of age. In four cases, however, a second transfusion was needed within a week. Overall, our data suggest that the response to maternal platelets is generally satisfactory. Our findings are in accord with previous observations which have suggested a better response to the maternal platelets as compared to the platelets from a random donor.[11,12] None of the newborn received platelets from a random donor in our series and we thus could not compare transfusion response according to the type of donor.

Serologically, platelet reactive antibody could be demonstrated in 90% of cases in our series. The platelet immunofluorescence test appeared to be more sensitive than ELISA for this purpose. In one reported series of 30 cases of ANT, platelet antibodies were also detected best by the immunofluorescence test.[13] Also, the maternal fetal incompatibility for platelet specific antigen $P1^{A1}$ was found in 83% of cases. This is in contrast to our cases in which the $P1^{A1}$ incompatibility was only 50%. It should be noted that low rates of $P1^{A1}$ incompatibility that we observed were also noted by others.[14] There is no apparent explanation for these differences. Further studies are needed not only to clarify these differences but also to elucidate the incompatibility for platelet antigens other than $P1^{A1}$.

The presence of lymphocytotoxic HLA antibodies in maternal sera was commonly seen in our study. In two cases (case #7 and 8) only the platelet antibody in the absence of lymphocytotoxic antibodies could be demonstrated. In six other cases, lymphocytotoxic antibodies were found and these could have reacted in ELISA or PIFT. A low incidence of lymphocytotoxic antibodies (13%) in maternal sera reported by von den Borne et. al. is in contrast to an incidence of 60% that we have found. These differences might be due to the fact that the size of our panel to screen for such antibodies was larger (40-60 vs 35-39). In addition, 80% of mothers in our series had more than one pregnancy. This information is not presented in the paper by von den Borne et. al. This may also account for a higher incidence found in our study. It should be noted that an incidence similar to ours has been found in a larger series reported by Aster.[14]

The question of the role of HLA antibodies in the causation of ANT[1] remains doubtful. The high incidence of HLA antibodies in mothers is most likely coincidental. In fact, the information that we have obtained in one case (Case #2) seems to contradict the role of HLA antibodies in ANT. The mother in case #2 had delivered a baby with ANT three years previously and the baby had required maternal platelet transfusion. The mother's serum at that time had demonstrated the presence of anti-HLA-A2. Mother's HLA-type was A1, 26; B27, W57. The affected baby's HLA type obtained at 3 years of age showed A1, 3; B27, W57 phenotype. In view of the absence of HLA antigen A2 in the affected baby, it could be concluded that ANT was not due to maternal anti-HLA-A2 antibody.

Our findings in 10 cases of alloimmune neonatal thrombocytopenia suggest that the newborns most often have severe thrombocytopenia with mild bleeding manifestations. A prompt treatment with the maternal platelets generally gives good results although the duration and extent of response is variable. Therefore, the serial daily platelet counts should be obtained to assess the need for a repeat platelet transfusion and to detect spontaneous recovery in this self-limited disorder. The presence of platelet reactive antibody in the maternal sera can be demonstrated in 90% of cases. In approximately half the cases, alloimmunization to $P1^{A1}$ antigen is possible since three of the six mothers tested were negative for $P1^{A1}$ antigen. The maternal allosensitization to HLA antigens can also be shown in a majority of cases. Therefore, there is a possibility that the maternal-fetal-incompatibility for the HLA antigens may be responsible for ANT. Further studies designed to assess the pathogenesis of this disease in relation to platelet and HLA alloimmunization would be desirable.

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Prolonged Venous Access in Cancer Patients: A Review of Currently Used Modalities

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Introduction

Venous access in cancer patients sooner or later proves to be a dilemma to both patients and to those providing their care. The need for chronic intravenous therapy by which toxic antineoplastic agents, antibiotics, transfusions and parenteral nutrition are delivered, rapidly exhaust peripheral veins, making the use of plastic intravenous catheters or the technique of rotating small steel needles[2] which themselves are associated with high rates of phlebitis and infection, ineffective. Utilization of arteriovenous fistulas have generally been unsuccessful due to a high rate of failure because of an increased likelihood of thrombosis in patients without renal failure.[5,6,17,20]

The Broviac catheter[6,18] was a major innovation in providing long term venous access. It offers decreased thrombogenecity secondary to the silastic material with which it is constructed and a reduced infection rate believed to be promoted by the bacterial barrier formed by exiting the catheter through a subcutaneous tunnel, coupled with the addition of a Dacron Cuff with which fibrous adhesions are formed. Hickman subsequently modified this catheter, enlarging its internal diameter to 1.6 mm, thus facilitating the administration of blood products and enhancing the volume which could be infused.[8] A more recent development is a totally implantable central venous access system (Port-A-Cath), composed of a silastic catheter connected to a small volume subcutaneous injection port.[4]

Oncology patients, with their exposure to myelotoxic chemotherapeutic agents, present special problems in terms of immunosuppression and bleeding derangement. Their increased susceptibility to infection and assumed predisposition to significant complications with the use of chronic central venous access systems have been questioned. This study is comprised of a retrospective review of all patients undergoing Hickman catheter or Port-A-Cath insertion at Waterbury Hospital Health Center over a three-year period. Two groups of patients were designated. The first was composed of those undergoing treatment of malignancies. The second was composed of patients being treated for benign disease. Relative complication rates between the two groups were compared and the feasibility of using these types of venous access devices in cancer patients examined.

Method

The medical records of 61 patients undergoing Hickman catheter or Port-A-Cath (Pharmacia Laboratories, Piscataway, New Jersey) insertion during the time period extending from January, 1981, through December, 1984, at this institution were reviewed. Forty-five of these patients were treated for malignancies, the remainder for benign disease. Evaluated were: 1) indications for long term venous access, 2) techniques for insertion, 3) catheter longevity, and 4) associated complications. All complications attributable to any kind of catheter dysfunction were recorded. Catheter infections were divided into categories of superficial infection defined by erythema and induration confined to the skin in the region of the subcutaneous tunnel and exit site through which the catheter traverses, and catheter-related sepsis determined by the presence of positive cultures in the absence of other possible sources. Statistical analysis of data obtained

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was performed by use of the student's t and chi-square test.

Results

Sixty-three Hickman catheters and four Port-A-Caths were placed in 61 patients over this time. Of 45 oncology patients, 13 were male (20%), and 32 were female (71%). Ages ranged from 3 to 77 years with a mean age of 51 ± 7 years. Eleven patients were treated for leukemia, nine for various lymphomas, nine for breast carcinoma, five for colonic carcinoma, three for ovarian carcinoma, one for esophageal carcinoma, one for gastric carcinoma, one for pancreatic carcinoma, one for mesothelioma, one for Wilm's Tumor, one for testicular carcinoma, one for squamous cell carcinoma of the tongue, and one for malignant melanoma. Indications for catheter placement were primarily for chemotherapy (80%), parenteral nutrition (11%), or for a combination of these (4%). One patient had a Hickman catheter placed for the administration of analgesia (2%) and another for antibiotic therapy (2%).

The diagnoses in 16 patients treated for benign disease included: Crohn's Disease-5; intracerebral hemorhage-2, short bowel syndrome-1, ulcerative colitis-1, head injury-1, aplastic anemia-1, dysplastic anemia-1, hemachromatosis-1, Laennec's cirrhosis-1, *Mycobacterium avium* infection-1, and Gram Negative Sepsis with renal failure-1. Catheterization was performed in this group primarily for parenteral nutrition (56%) or antibiotic therapy (25%). Catheters were also placed for purposes of transfusion (12.5%) and in the case of the patient with hemachromatosis, for repeated phlebotomy (6%). Seven patients in this group were male (44%), and nine were female (56%). Ages ranged from 13 to 82 years with a mean of 47 ± 6.6 years.

Technique of catheter insertion was predominantly via cutdown on the cephalic vein within the deltopectoral groove (33), external jugular vein (11), or internal jugular vein (13) with primarily local anesthesia. Catheters were placed directly in the subclavian vein via a percutaneous stick on four patients. In one patient, attempted catheterization via a vessel in the neck or shoulder was unsuccessful secondary to Superior Vena Cava Syndrome resulting from a metastatic mesothelioma. The catheter was thus inserted through a peripheral vein in the antecubital fossa of the arm, feeding its tip medially to a central location. Catheter placement in the superior vena cava near its junction with the right atrium was otherwise confirmed intraoperatively in all cases with the use of fluoroscopy. Subcutaneous tunnels were performed either by blunt dissection with a long Kelley clamp or by use of a trochar from a large Hemovac apparatus. Perioperative antibiotic prophylaxis was used sporadically in both groups.

In total number of days of catheterization in the group of patients with malignancies was 9,967 with the longest duration of catheterization being 955 days. This was a patient with Hodgkin's lymphoma whose Hickman catheter is still functioning well. The average duration in this group of patients was 221.5 ± 14.7 days. Fifty-eight percent of patients in this group experienced uninterrupted use of their catheters until either elective removal or death. Twenty-two percent still have their original catheters in place, reporting no history of catheter dysfunction.

In the group of patients with benign disease, the number of catheterization days totaled 2,801, with a mean duration of 175 ± 8 days. Fifty-six percent of patients in this group experienced uninterrupted use of their catheters until removal or death. Original catheters are still present in 25%, exhibiting continuous function since their time of insertion.

Catheter infection, both catheter-related sepsis and superficial infection, comprised the most serious complications in both groups. Other complications that were encountered included catheter occlusion, fracture of the external segment necessitating repair, one episode of erosion of the dacron cuff through the skin, and in one patient, required evacuation of a subcutaneous hematoma in the immediate postoperative period. No episodes of clinical vessel thrombosis or dislodgement of the distal segment out of the superior vena cava was observed. In the group treated for malignancies, 11 complications were seen in ten patients. Catheter infections comprised six of these. One superficial infection was treated solely with antibiotics. The remainder were treated by catheter removal as well, though only three of the infections were confirmed by positive cultures. Two patients received multiple catheters. One patient, who had a Hickman catheter inserted through the anticubital fossa due to Superior Vena Cava Syndrome, necessitated recurrent catheter replacement on two occasions for episodes of catheter occlusion and infection respectively. Another patient electively chose to have her Hickman catheter which had been functioning well replaced with a Port-A-Cath. Twenty-five deaths occurred in this group of patients, none of which could be attributable to a possible catheter complication. The infection rate in this group of patients was .06 infections per 100 catheter days. The total complication rate equalled 0.11 complications per 100 catheter days.

Of patients treated for benign disease, six complications were encountered in three patients. Catheter infections accounted for two of these. In both cases, catheters were removed. Two patients received multiple catheters, one of these underwent replacement for his catheter twice, once for catheter occlusion and again for superficial infection. Three patients in this group died over the period investigated, none as a result of catheter complications. The infection rate in this group was 0.07 infections per 100 catheter days.

The total complication rate was 0.21 complications per 100 catheter days.

A total of four Port-A-Caths were placed during this study period, split evenly between both groups of patients. One patient with Hodgkin's Disease experienced uninterrupted use of her catheter until death. The remaining three patients currently have catheters in place with a mean duration of 364 ± 15.5 days, experiencing no complications whatsoever since the day of their insertion.

Discussion

Analysis of the data obtained through review of 61 patients undergoing Hickman catheter or Port-A-Cath insertion as a means of securing long term venous access at our institution reveals no statistical difference ($P = .05$) between groups of patients treated for malignant versus benign disease in terms of catheter longevity, infection rate, and total complication rate. Furthermore, the low infection rate (0.06 infections per 100 catheter days in cancer patients; 0.07 infections per 100 catheter days in non-cancer patients), and low total complication rate concur with prior reported figures by early investigators (infection rate ranging 0.00 to 0.80 infections per 100 catheter days; complication rate averaging 0.3 complications per 100 catheter days)[1,7,8,10,12,13,14,16] attesting to the feasibility of utilizing this modality in oncology patients. The extended longevity of uninterrupted and uncomplicated use demonstrated by some patients further supports this contention.

No specific risk factors were isolated that could be attributed to any increased incidence of complication except in one patient where placement of the catheter within the antecubital fossa of the arm was obviously associated with an increased rate of catheter thrombosis and infection. This was likely due to the increased mobility of the region coupled with the difficulty encountered in trying to keep the area about the catheter exit site clean. Hickman et al; have reported that insertion of a catheter in the presence of fever, distant sites of infection, or neutropenia, such as is provoked with chemotherapy in cancer patients, was not associated with any increased rate of catheter infection. Furthermore, no benefit to the use of prophylactic antibiotics could be determined.[12]

Perhaps the most significance in procuring adequate catheter longevity is patients' education and instruction on the proper care and maintenance of their catheter. Recommendations, as had been priorily outlined by Ivey and Reed,[9,14] describe daily flushing of the catheter with heparinized solution coupled with meticulous catheter exit site care and daily dressing changes. At our institution, patients are instructed to flush their catheters every two to three days or more frequently depending on their level of activity. Dressing changes about the catheter exit sites are performed at least once a week or whenever the dressing becomes loose or soiled.

The most common infecting organism observed in this review was *Staphylococcus epidermidis* (4/6 catheter infections confirmed by positive cultures), followed by *Staphylococcus aureus* (2/6 confirmed catheter infections). Five catheters were removed as a consequence. Recent recommendations, made by Hickman et al,[12] are that generally infections involving the subcutaneous tunnel or septic thrombophlebitis required catheter removal. Otherwise, antibiotic therapy should be attempted first, particularly in patients where continued venous access will be necessary. Forty-eight hours should be allowed before making further judgment on subsequent catheter removal should there be no clinical improvement in terms of local inflammation, fever and bacteremia.

Though the number of Port-A-Cath catheters inserted was limited, our experience with this totally implantable apparatus has generally been favorable. The mean duration for catheterization with this device was 316 ± 15.4 days, with no recorded complication. Three out of four patients still have their catheters in place, enjoying uninterrupted use. Optimism exists that the Port-A-Cath will offer an unencumbering modality for venous access, tailor-made for the more active patient, providing patient convenience with a low rate of complication as initially shown by Bothe.[4]

Summary

Sixty-one patients underwent Hickman catheter and/or Port-A-Cath insertion as a means of procuring long term venous access. The patients were separated into groups treated for malignancies versus benign disease. Comparison of complication rates between the two revealed no statistical difference, especially in rates of catheter infection. Furthermore, acceptably low complication rates concurring with prior reports by early investigators support continued utilization of these devices in oncology patients. Data reviewed suggested significant catheter longevity (mean 221.5 ± 14.7 days) further attesting to the feasibility in its use as a mode of securing long term venous access. Discussed as well was the need for adequate patient instruction on the care and maintenance of their catheter. Current recommendations for management of catheter infections were reviewed.

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Statistics in Medicine—The Master's Viewpoint

As for statistics, they are given a great rôle in medicine, and they therefore raise a medical question which we should examine here. The first requirement in using statistics is that the facts treated shall be reduced to comparable units. Now this is very often not the case in medicine. Everyone familiar with hospitals knows what errors may mark the definitions on which statistics are based. The names of diseases are very often given haphazard, either because the diagnosis is obsecure, or because the cause of death is carelessly recorded by a student who has not seen the patient, or by an employee unfamiliar with medicine. For this reason pathological statistics can be valid only when compiled from data collected by the statistician himself. But even then, no two patients are ever exactly alike; their age, sex, temperament and any number of other circumstances involve differences, with the result that the average, or the relation deduced from our comparison of facts, may always be contested. But I cannot accept even the hypothesis that facts can ever be absolutely alike and comparable in statistics; they must necessarily differ at some point, for statistics would otherwise lead to absolute scientific results, while they can actually show only probability, never certainty. I acknowledge my inability to understand why results taken from statistics are called *laws;* for in my opinion scientific law can be based only on certainty, on absolute determinism, not on probability. I should stray from my subject, if I went to all possible explanation of the value of statistical methods based on the calculus of probabilities; yet I cannot but say here what I think about the application of statistics to physiological science in general and to medicine in particular.

—Claude Bernard, *An Introduction to the Study of Experimental Medicine*, 1865.

Conduction System Study in a Patient with Rheumatoid Arthritis

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AND GERALD A. GORECKI, D.P.M., M.P.H.

ABSTRACT—Conducting system involvement by rheumatoid arthritis was demonstrated in a patient who died suddenly twenty-four hours after surgical repair of a deformed foot. While fatal arrhythmias are a rare complication of rheumatoid arthritis, cardiac involvement with arrhythmias has been shown not to be uncommon in rheumatoid patients with a history of vasculitis. The importance of studying the cardiac conduction system in such patients is therefore emphasized.

Introduction

Cardiac involvement is an uncommon complication of rheumatoid arthritis, though it is far more prevalent among rheumatoid patients with evidence of vasculitis.[1] Twenty-eight cases of complete heart block in patients with rheumatoid arthritis have been reported,[2,3] and lesser degrees of block are more frequently observed.[4] These arrhythmias have been found to be associated with inflammatory lesions within the cardiac conduction system.[2,3] These lesions could possibly, under certain circumstances, be triggered and produce a fatal arrhythmia. Special attention is therefore necessary, at autopsy, for examination of the cardiac conduction system. The present report demonstrates the value of such an examination.

Case Report

A 64-year-old male, retired die and mold maker was admitted to the West Haven Veterans Administration Medical Center for elective foot surgery because of painful and deformed feet secondary to seropositive rheumatoid arthritis.

His disease was controlled by prednisone (5 mg. twice daily), indomethacin (25 mg. four times daily), and penicillamine (250 mg. three times daily). His arthritis predominantly involved the hand, knee, ankle and foot joints. In 1980, he was hospitalized with multiple rheumatoid vasculitic left leg ulcerations which responded to steroid cream. In 1983, he underwent placement of silastic hinge implants in the metacarpophalangeal joints of the right hand.

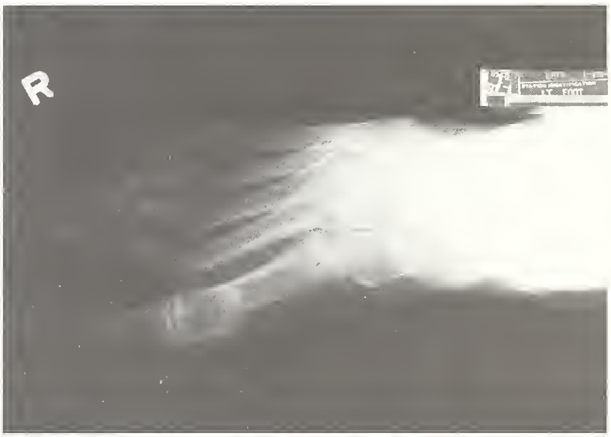

Figure 1
Dorsoplantar, weightbearing preoperative roentgenogram of the right foot. Note the erosions and the subluxation of all the metatarsophalangeal joints.

His past medical history was remarkable for passage of a renal stone in 1976 and a cholecystectomy for cholelithiasis in 1981. He had a 40 pack year history of cigarette smoking. On admission, he appeared well except for his joint deformities. No lymphadenopathy or nodular lesions were found. Bilateral mild chest wheezes were noted and cardiac exam was normal. The upper extremities revealed evidence of his previous right hand surgery with the left hand demonstrating mild swan-neck deformities. The lower extremities showed prominent metatarsal heads with

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tender metatarsophalangeal and ankle joints. The first metatarsophalangeal had significant crepitus with dorsiflexion. All lesser digits demonstrated hammer toe deformities with subluxation at the metatarsophalangeal joints (Figure 1). All signs, symptoms and deformities were more prominent on the right.

Laboratory examination was remarkable for a creatinine of 1.8 (normal range 0.8-1.5) with a normal urinalysis. An electrocardiogram showed left ventricular hypertrophy. Chest X-ray was reported as unremarkable. He underwent a right pan-metatarsal head resection (Hoffman-Clayton procedure) under local anesthesia and intravenous sedation. A postoperative compression-shell short-leg cast was applied. During the operative period, he was placed on corticosteroid supplementation, and maintained on his usual dosages of indomethacin and penicillamine.

No complications were noted on the first postoperative day. At 6:50 a.m. on postoperative day two, he stated to the nurse that he was nauseous from his morning medications and vomited a small amount of bile-colored material. Approximately ten minutes later he was heard to have fallen in bed and was found unresponsive, pale, and cyanotic without blood pressure, pulse, or respirations. An electrocardiogram initially showed some sinus complexes but then rapidly deteriorated to ventricular fibrillation. Extensive resuscitative efforts were unsuccessful and he was pronounced dead at 8:12 a.m.

Figure 2a
Low-power view of rheumatoid nodule, showing typical palisaded histiocytes and lymphocytes around a hyalinized center. Section from the septum at atrioventricular junction (H & E, 4x).

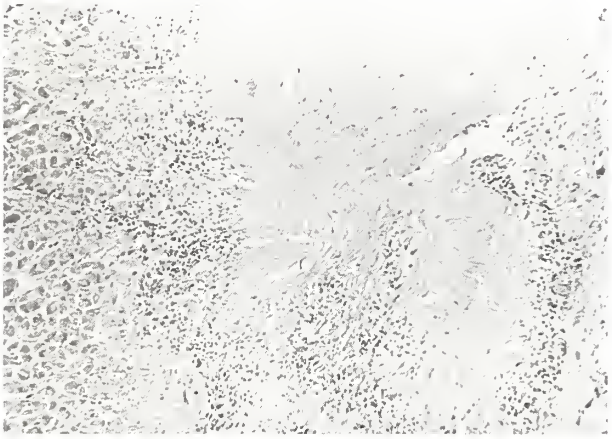

Figure 2b
Higher power view of rheumatoid nodule showing inflammatory cells involving the upper interventricular septum bundle of His (H & E, 10x).

Pathological Findings

Autopsy revealed a 500 gm. heart with concentric left ventricular hypertrophy. No grossly apparent lesions of the myocardium or valves were noted, and the coronary arteries showed only mild, hemodynamically insignificant atherosclerosis. However, sections taken from the conduction system and especially the region of the A-V node just above the septum membranaceum, as well as the bundle of His, which is the only muscular connection between atria and ventricles, showed extensive rheumatoid carditis with fibrosis, chronic inflammation, and rheumatoid nodules (Figure 2A, B). Stains of these sections for acid-fast and fungal organisms were negative. Other sections of myocardium revealed only occasional mild perivascular lymphocytic infiltrates.

Examination of the lungs revealed an acute, necrotizing bronchopenumonia in the left lower lobe with small aggregates of squamous cells and foreign material within some air spaces, consistent with aspiration. No evidence of pulmonary embolus was seen grossly or microscopically. The apex of the left lung showed a focal pleural-based scar with fibrotic nodules which on polarization showed numerous birefringent silicotic particles. Stains for acid-fast and fungal organisms were negative. Similar silicotic nodules were seen in hilar lymph nodes (Figure 3A,B);

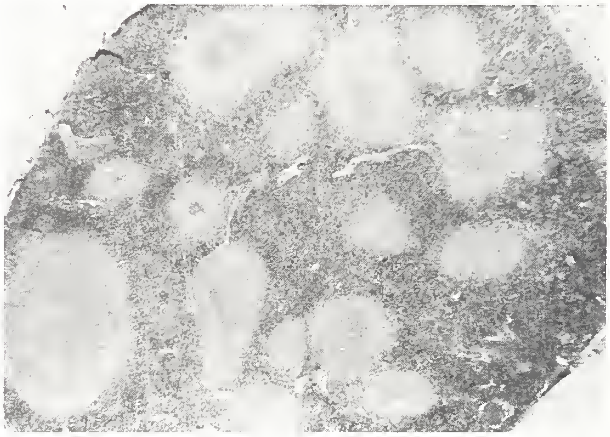

Figure 3a
Photomicrograph of mediastinal lymph node showing multiple different sized fibrotic nodules (H & E, 4x).

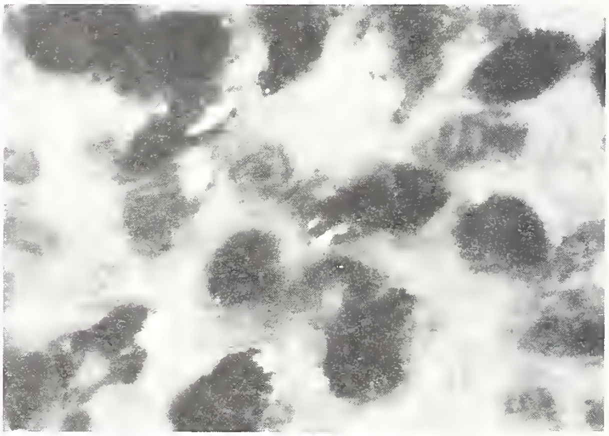

Figure 3b
High-power view of polarized silica crystals in mediastinal lymph node (100x).

these nodules likewise contained birefringent particles whereas such particles were not seen in the rheumatoid nodules in the heart.

Additional findings at autopsy included bilateral renal stones and small adrenals (5 gms. each) with thin cortices, the latter finding being consistent with the patient's history of corticosteroid therapy. No other rheumatoid nodules were seen, although a focal perivascular lymphocytic infiltrate was found associated with a medium-sized artery in the muscularis propria of the esophagus.

Discussion

The finding of rheumatoid nodules in the conduction system of the heart without any evidence of pulmonary embolus or ischemic heart disease strongly suggests that the cause of this patient's sudden death was an arrhythmia. While fatal arrhythmias are an extremely rare complication of rheumatoid arthritis, cardiac involvement is not infrequent in those rheumatoid arthritis patients who, like this man, have evidence of vasculitis. In a recent review of 50 patients with rheumatoid vasculitis, 17 were found to have cardiac involvement, with nine of these having arrhythmias.[1] Villecco et al.[5] found antibodies to cardiac conducting tissue in 16 of 21 patients with rheumatoid arthritis and right bundle branch block. More recently, Ahern et al.[2] reviewed 28 cases of complete heart block in patients with rheumatoid arthritis. In most of these cases, the onset of the arrhythmia was sudden, though it was by no means uniformly fatal. In the 19 patients in whom pacemakers were inserted, only two died within 24 hours and 11 survived longterm. The arrhythmia was fatal in eight of nine patients who did not receive pacemakers, however even in these cases death was not always sudden.

Histologic study of the conduction system at autopsy in rheumatoid arthritis patients with complete heart block has revealed classic rheumatoid granulomas in some, but not all cases, with the other cases showing fibrosis with chronic inflammation.[2,3] The lesions found at autopsy in the case reported here clearly fall within the range of those described in the above literature. However, it is also clear from the histological appearance of the cardiac lesions that they must have been present for some time. What role, if any the stress of the surgical procedure and the patient's postoperative pneumonia may have had played in the lesion manifesting itself as an arrhythmia is unclear. In one of the patients reported by Ahern et al.,[2] the initial onset of an arrhythmia appeared to be temporally associated with cervical spinal cord compression, and septicemia due to urinary tract infection.

The finding of fibrotic nodules in the left lung and hilar lymph nodes raises the question of whether these too are related to the patient's rheumatoid arthritis. While pulmonary rheumatoid nodules occur only rarely among patients with even severe rheumatoid arthritis, it has been reported that these are more likely to develop in rheumatoid patients with concurrent silicotic lung disease.[6,7] While the pulmonary rheumatoid nodules in some of these cases were noted to contain silica granules, their histologic appearance was generally that of typical rheumatoid nodules, with dense fibrosis, varying degrees of central necrosis, and a surrounding palisade of fibroblasts and chronic inflammatory cells.[7] In contrast, the nodules found in the lung and hilar lymph nodes in the present case lack these latter features, and thus appear simply to be old silicotic nodules.

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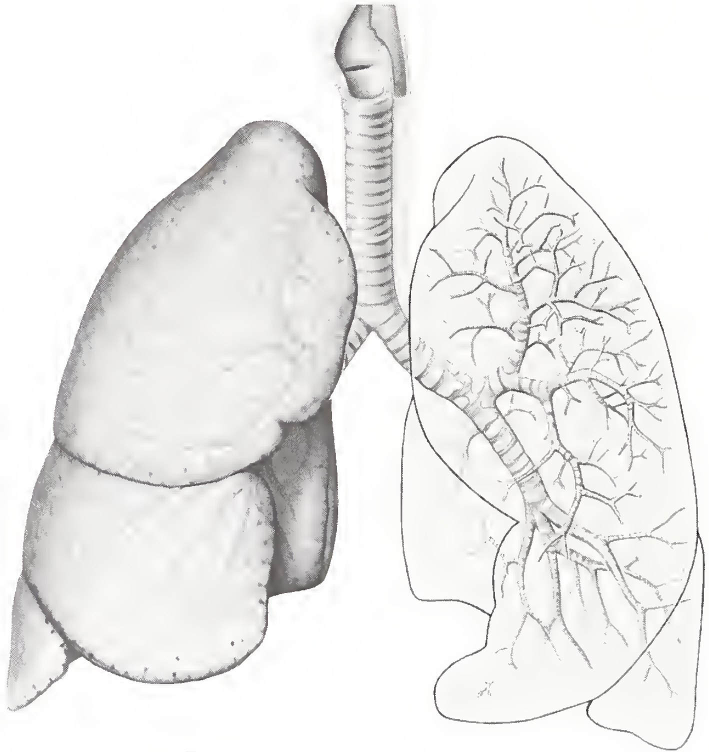
Consider the causative organisms...



Ceclor®
cefaclor

250-mg Pulvules® t.i.d.

offers effectiveness against the major causes of bacterial bronchitis

H. influenzae, *H. influenzae*, *S. pneumoniae*, *S. pyogenes*
(ampicillin-susceptible) (ampicillin-resistant)

Brief Summary Consult the package literature for prescribing information

Indications and Usage: Ceclor® (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae*, and *S pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor

Contraindication. Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics

Warnings IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins), therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics Such colitis may range in severity from mild to life-threatening

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C difficile* Other causes of colitis should be ruled out

Precautions: *General Precautions* – If an allergic reaction to Ceclor® (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g , pressor amines, antihistamines, or corticosteroids

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms Careful observation of the patient is essential If superinfection occurs during therapy, appropriate measures should be taken

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug

Ceclor should be administered with caution in the presence of markedly impaired renal function Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly)

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis

Usage in Pregnancy – Pregnancy Category B – Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor® (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed

Nursing Mothers – Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses Average levels were 0 18, 0 20, 0.21, and 0 16 mcg/ml at two, three, four, and five hours respectively Trace amounts were detected at one hour The effect on nursing infants is not known Caution should be exercised when Ceclor is administered to a nursing woman

Usage in Children – Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment Nausea and vomiting have been reported rarely

Hypersensitivity reactions have been reported in about 1 5 percent of patients and include morbilliform eruptions (1 in 100) Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor Such reactions have been reported more frequently in children than in adults Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy No serious sequelae have been reported Antihistamines and corticosteroids appear to enhance resolution of the syndrome

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients)

Causal Relationship Uncertain – Transitory abnormalities in clinical laboratory test results have been reported Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician

Hepatic – Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic – Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal – Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

Note Ceclor® (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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400441

Important Advances in Clinical Medicine

Epitomes of Progress—Neurology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in neurology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in neurology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Neurology of the California Medical Association and the summaries were prepared under its direction.

Intellectual and Behavioral Effects of Anticonvulsants

Most of the major anticonvulsants, especially when used in combination, may interfere with intellectual function and behavior, at least in subtle ways. Attention, concentration, intellect, sociability, mood and motor activity may all be affected to some extent by these pharmacologic agents. For many patients with epilepsy the treatment becomes as much a problem as the disease.

Phenytoin

Familiar side effects from phenytoin include dysequilibrium and an actute encephalopathy. A more insidious impairment of mental function may occur without the usual clinical signs of phenytoin intoxication and in the face of therapeutic blood concentrations. This problem has occurred most frequently in children with brain damage and may be mistaken for progressive degenerative neurologic disease. Decline in IQ has been found. In adults progressive dementia may be mimicked, and an electroencephalogram may show excessive slowing. The syndrome is reversible with reduction of dosage or discontinuation of phenytoin therapy. Similar mental changes have been produced in subjects receiving phenytoin in the absence of epilepsy.

Barbiturates

Barbiturates have long been known to produce behavioral disturbances in children, especially hyperactivity, aggressive behavior, tantrums, sluggishness and disobedience. These complications may be seen in half of the children taking barbiturates and are troublesome enough to limit the usefulness of this medication, especially for relatively benign conditions such as febrile seizures. These behavioral disturbances are rapidly reversible with reduction of dosage or discontinuation of the use of barbiturates.

Benzodiazepines, Ethosuximide, Valproate, Carbamazepine

Benzodiazepines have side effects similar to those of barbiturates such as irritability, aggression and hyperactivity. Ethosuximide can produce psychosis or encephalopathy. Stupor and drowsiness occur occasionally with the use of valproate sodium. Significant behavioral disturbances are rare with the administration of carbamazepine and are found most frequently in patients with brain damage who are also receiving other anticonvulsants. Because intellectual and behavioral effects are unusual with the use of carbamazepine, that anticonvulsant may be the drug of first choice for tonic-clonic and partial complex seizures, at least in children.

Monotherapy

Many of these side effects are related to the use of several drugs in anticonvulsant therapy. By withdrawing multiple drugs and instituting a single drug, a clinician can frequently reduce or eliminate the intellectual and behavioral effects without significant harm to

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seizure control. Monotherapy is often the most effective method of seizure control, even for frequent seizures.

It must be stressed that intellectual and behavioral effects, sometimes subtle and sometimes resembling progressive neurologic deterioration, can occur at therapeutic anticonvulsant blood concentrations in persons with epilepsy. The benefits of therapy must outweigh the negative intellectual and behavioral effects. However, not all intellectual and behavioral abnormalities in epileptic children are related to medication; brain damage and social problems are often complicating factors irrespective of pharmacologic intervention.

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Alzheimer's Disease
(Senile Dementia of the Alzheimer Type)

In 1983 the number of persons in the United States older than 65 years surpassed the population of teenagers. By the year 2030, it is estimated that those older than 65 will make up about 20% of the total population—that is, *about 50 million persons.*

When elderly people begin to suffer memory lapses or periodic confusion, these symptoms are most often blamed on "old age" or senility, but may simply be "benign forgetfulness." The most serious common form of *acquired* mental deterioration is Alzheimer's disease, which probably affects more than 500,000 persons in the United States older than 40 years. The incidence increases with age (2% from 65 to 70 years; 4% from 70 to 80 years; 20% older than 80 years), but it is not synonymous with advancing age or senility. Siblings of patients have a 3.8% risk of having the disease; children of parents who have Alzheimer's disease have a 10% risk. Of interest is that there is an elevated frequency of Down's syndrome as well as leukemia and Hodgkin's disease among family members.

Senile dementia of the Alzheimer type was first described almost 80 years ago by a German neuropathologist and neurologist, Alois Alzheimer. The pathologic features are a loss of cortical and certain subcortical neurons, neurofibrillary tangles and senile plaques. It is a painless, progressive illness that commonly presents initially as a loss of memory and an inability to learn new material. Personality, behavioral and motor changes, such as rigidity or paralysis, and incontinence occur rather late in its evolution. Life expectancy is shortened. Death is commonly due to intercurrent infections, usually at a time when the patient is mute, withdrawn and requiring constant nursing care.

The cause of Alzheimer's disease is obscure. The most popular theories concern "slow viruses," "prions" (protein-aceous infectious particles) and disorders of the immune system, but *not* aluminum toxicity as once suggested. A decrease of choline acetyltransferase, somatostatin and norepinephrine content in the neocortex has been shown in some patients. There are no characteristic blood, urine or cerebrospinal fluid abnormalities. Electroencephalograms and computed tomographic scans show nonspecific abnormalities in the advanced stages. Position-emission tomography and nuclear magnetic resonance are more likely to detect early abnormalities. Psychological testing shows changes consistent with "cortical" dementia. Because of the large number of conditions that can cause mental deterioration in adults, the diagnosis of Alzheimer's senile dementia is one best made by exclusion of other causes, of which about 10% are treatable. It is important to recognize and treat depressed patients who may present with dementia initially.

There are no specific treatments at present. Management involves guidance to family members and friends, treatment of intercurrent medical and behavioral problems and nursing home admission when a patient can no longer be cared for at home. Support groups exist in most large communities under the direction of: Alzheimer's Disease and Related Illnesses Foundation, 360 N Michigan Ave, Suite 601, Chicago, IL 60601.

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Anticoagulation Therapy for Cardiogenic Cerebral Emboli

The question of when to use anticoagulation therapy epitomizes the controversy surrounding the clinical management of stroke. Anticoagulation is often used routinely for stroke prophylaxis and urgent intervention even when solid evidence to support this therapy is lacking. There is, however, one clinical setting in which anticoagulation is definitely beneficial: preventing initial and recurrent cerebral emboli from a recognized cardiac source.

Chronic atrial fibrillation in the presence of rheumatic valvular disease is associated with a 17-fold increased risk of stroke in previously asymptomatic patients, and long-term anticoagulation appears to decrease this by 80% to 90%. Nonvalvular chronic atrial fibrillation carries a fivefold to sixfold increased stroke risk for asymptomatic patients; studies to establish a benefit from anticoagulation are currently in progress. Of patients with acute myocardial infarction, about 5% will suffer cerebral emboli in the first six weeks and remain at risk indefinitely even after that period; anticoagulation significantly decreases their risk of embolic stroke.

Patients having acute embolic stroke from a cardiac source are at high risk for recurrent emboli, particularly in the first week; this seems to be largely independent of the nature of their underlying cardiac disease. In general, immediate anticoagulation with heparin can be given safely and effectively in such cases, given that a noncontrasted computed tomographic (CT) scan of the head shows no evidence of hemorrhage. In a patient with clinical evidence of a large ischemic infarction, however, anticoagulation should be delayed until the CT scan is repeated in four to seven days; this is done specifically to rule out delayed spontaneous hemorrhage, an increasingly recognized complication of large embolic infarctions.

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Sensory Evoked Potentials

The clinical evaluation of patients with neurologic problems is subjective and based on semiquantitative data. Computed tomography (CT), other radiologic procedures, electroencephalography (EEG), electromyography and, in the future, nuclear magnetic resonance imaging contribute to the diagnostic acumen. An objective, noninvasive evaluation of specific spinal cord and brain sensory pathways has become available in clinical practice through the application of sensory evoked potential (EP) techniques. Sensory evoked potentials are the electrical responses of the nervous system to specific external stimuli that activate afferent pathways. These potentials are of very low amplitude, which requires that they be extracted from the much larger ongoing EEG activity using computer averaging techniques. Applications of clinical use are (1) cortical visual evoked potentials elicited by reversing pattern stimulation, (2) click-evoked brain-stem auditory evoked potentials and (3) electrically elicited subcortical and spinal somatosensory evoked potentials.

Visual Evoked Potentials

The primary usefulness of visual EPs is in cases of multiple sclerosis because the optic nerve is frequently involved in this disorder, even in asymptomatic patients, and abnormalities tend to persist after clinical recovery. The diagnosis of multiple sclerosis requires evidence of multifocality. Visual EPs often provide that information. In patients without clinical evidence of optic nerve involvement, visual EPs are abnormal in 40% to 50% of cases of possible and probable multiple sclerosis and in 50% to 60% of cases of definite multiple sclerosis. In other lesions of the optic nerve, visual EPs are not as useful because involvement is often clinically apparent or detected more easily by other techniques. Intraoperative monitoring of patients with tumors in or around the optic nerve is helpful in selected patients. Visual EPs are not helpful in the evaluation of coma.

Brain-stem Auditory Evoked Potentials

Brain-stem auditory EPs are not as useful in cases of multiple sclerosis, but the detection rate of silent lesions is still about 20% to 30%. This technique is excellent in the early detection of acoustic neuromas and invasive brain-stem gliomas. The yield in detecting acoustic neuromas, even very small ones not visualized by contrast brain CT scan, is well over 90%. Normal findings on brain-stem auditory EPs, for all practical purposes, rule out an acoustic neuroma. In some selected patients brain-stem auditory EPs are used to monitor the functional integrity of the acoustic nerve during removal of an acoustic neuroma. This technique has not been useful in detecting vascular lesions of the brain-stem. In patients in coma, normal brain-stem auditory EPs are highly suggestive that the brain stem is functionally intact. Abnormal evoked potentials in a patient in coma imply that the primary cause of the coma is a structural brain-stem lesion.

Somatosensory Evoked Potentials

Somatosensory EPs are also excellent in detecting silent lesions in cases of multiple sclerosis. In patients without sensory symptoms or signs, somatosensory EPs will be abnormal in 50% with a definite diagnosis of multiple sclerosis, in 55% to 60% with a probable diagnosis and in 40% with a possible diagnosis. These percentages will be even higher when both upper and lower extremity stimulation is used. In addition to cases of multiple sclerosis, somatosensory EPs are sometimes of use to locate lesions in the peripheral nervous system, plexi, roots and spinal cord. Abnormalities will be present when posterior columns or the lemniscal system is involved. Because somatosensory EPs test different structures than brain-stem auditory EPs, they are helpful in evaluating cases of coma. Normal somatosensory EPs and brain-stem auditory EPs in a patient in coma make it extremely unlikely that the cause of the coma is a structural brain-stem lesion. Monitoring spinal cord function with somatosensory EPs in patients undergoing an extensive spinal operation is only feasible in centers with special expertise in this area.

Sensory EP studies can be of help in the diagnosis of neurologic disorders when used in situations as described above. Their indiscriminate use because they are available, relatively cheap and noninvasive should be discouraged.

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Arteriographic, Digital Angiographic and Noninvasive Testing of the Carotid Arteries

Just two years ago intravenous (IV) digital subtraction angiography was touted as a minimally traumatic method that would replace both standard head and neck arteriography and noninvasive tests in assessing disease in the carotid systems. Today it is clear that each neurodiagnostic technique has its place. Standard arteriography provides high-resolution images of the extracranial and intracranial vessels that cannot be achieved yet with IV or intraarterial digital subtraction angiography. The latter offer maximal contrast resolution, whereas the standard arteriographic techniques offer maximal spatial resolution. The noninvasive tests, using primarily ultrasound and plethysmographic methods, are the most sensitive procedures for detecting physiologic changes in the carotid and ophthalmic systems, which one can use to determine the hemodynamic effects of a carotid stenosis and to interpolate residual lumen diameter. Using noninvasive tests to monitor physiology is the safest and most practical way to follow patients for evidence of progression of a carotid lesion.

Although IV digital subtraction angiography is a relatively atraumatic technique and can be done on an outpatient basis, it carries associated local, systemic, cardiac and neurologic risks. Even when done well, the findings may be obscured by overlapping of vessels, poor cardiac output and subtraction and movement artifacts. The frequency of inadequate studies may increase with the occurrence of bilateral and tandem atheromatous lesions. Noninvasive tests are less traumatic and more routinely applicable, but not easy to carry out well. Neither noninvasive tests nor IV digital subtraction angiography provide data by which one can consistently distinguish between an occlusion and very tight stenosis or reliably identify ulcerations in an atheromatous plaque.

Patients with an asymptomatic bruit should be examined first with noninvasive testing. Patients with ischemic events in one vascular territory in whom noninvasive testing shows no evidence of contralateral or tandem lesions are candidates for IV digital subtraction angiography. If a patient has several signs or symptoms in several vascular territories or evidence of multiple lesions on noninvasive testing, an intraarterial contrast study is recommended. This should be a standard arteriogram unless selective catheterization is difficult. In the latter case, intraarterial digital subtraction angiography can facilitate the relatively rapid acquisition of information on the extracranial or intracranial extracerebral vessels using modest contrast volumes.

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Magnetic Resonance Imaging Versus Computed Tomography

X-ray computed tomography (CT) has revolutionized diagnosis and management. The information gained from CT scans has contributed to a reduction in the number of electroencephalograms, angiograms, spinal taps, plain skull films and isotope scans formerly done largely as nonspecific screening procedures. With the additional tomographic data available from magnetic resonance (MR) imaging, there will likely be a further reduction in these procedures.

A CT scan shows bone, blood and some grey and white matter distinction, but because the possible interactions of x-rays and tissues are limited, very little soft tissue characterization is possible. Magnetic resonance allows the imaging of hydrogen in tissues by applying a complex sequence of fixed and changing magnetic fields to a region of the body. A patient is placed in a very strong, constant magnetic field, several thousand times the earth's magnetic field. While this field is held constant, a high-frequency alternating current (in the shortwave radio range) is superimposed on this main field for a brief period. This excites hydrogen nuclei in the tissues. About two thirds of a body's atoms are hydrogen. The nucleus of the hydrogen atom behaves like a small bar magnet and tends to orient parallel to the main field. When excited by the radiofrequency pulse, some nuclei are driven out of alignment, returning to their original alignment after about one second. During this return, or decay, time they emit a radio signal at a frequency proportional to the magnetic field they are in. By adding and subtracting from the main field by electromagnetic coils placed around the patient, slight gradual changes (gradients) in field strength between two positions within the patient can be made that cause the resonant frequency of the decaying signal to be position-dependent. By this means, location and imaging of hydrogen in the body are possible.

Magnetic resonance excitation is usually by means of a sequenced pair of pulses separated by a brief interval. The computer expects tissue to be in the same place for both. If blood is moving rapidly, it will not be in the same place and will have been replaced by unexcited hydrogens. The chambers of the heart and the lumina of large vessels therefore appear dark. Blood's movement serves as its own contrast medium. It is reasonable to expect that most angiography (including coronary) eventually will be done by this noninvasive method. Within the limitations of patient movement, spatial resolution is as good as the best CT scan. Other characteristics of hydrogen's resonant frequency and rates of decay of the hydrogen signal provide still more information about tissue characterization.

Cortical bone contains very little hydrogen, so it appears black and is invisible on a scan. Many ordinarily obscured soft tissues such as bone marrow, pituitary, posterior fossa, spinal canal and inner ear structures can be seen with unprecedented clarity. Malignant tumors, edema and inflammation can be differentiated clearly from surrounding healthy tissues because tissue water in these regions is not only greater but appears to be relatively unbound to large molecules and cellular structures.

Magnetic resonance imaging produces so much information without the need to inject contrast material that there is little stimulus to develop new contrast media. And because there is no ionizing radiation, magnetic resonance appears to be completely harmless.

At present the greatest limitations of MR imaging are its long scan time (more than five minutes, making it inappropriate for many patients); its high cost (almost twice as much as a CT scanner); its low patient load (about half of that of CT); its complexity of theory, operation and interpretation (an order of magnitude greater than CT); its large space requirement (several times that of CT), and government resistance to this new technology.

The technology of CT was an order-of-magnitude jump over simple shadow radiography. Magnetic resonance appears to involve a similar jump beyond CT because it offers so much more information about tissues without subjecting patients to ionizing radiation. It should not be considered simply an extension of x-ray CT.

Because it is not radiologic in nature and is so complex, MR imaging will offer so much information to so many specialties that the performance and interpretation of this remarkably diverse new clinical probe of tissues inevitably will become interdisciplinary and not confined to any one specialty.

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Percutaneous Glycerol Trigeminal Gangliolysis for Tic Douloureux

Tic douloureux is a well-known syndrome of facial pain usually characterized by unilateral, paroxysmal, lancinating, electric shock-like pains in the distribution of one or more branches of the trigeminal nerve. The pain is unique in that it is frequently evoked by nonnoxious ipsilateral (trigger zone) stimulation, and neurologic examination shows little detectable trigeminal sensorimotor deficit. Episodes of pain last only seconds but recur with a variable frequency, usually in clusters and lasting from days to months. There are often spontaneous remissions for weeks, months or years between flurries of attacks.

About 70% of patients will obtain relief with the use of either carbamazepine or phenytoin. Thus, in about 30% of patients, medication is either ineffective or produces serious side effects necessitating discontinuance. These patients, therefore, may be candidates for the various surgical procedures that have been designed to treat tic douloureux. The mainstays of surgical therapy for this disorder are microvascular decompression of the trigeminal nerve via posterior fossa craniectomy, or percutaneous radiofrequency trigeminal gangliolysis. The former procedure has the potential of producing long-lasting pain relief without facial sensory loss, while the latter procedure avoids the risks of craniectomy and can be repeated easily if tic pain recurs.

Recently, retrogasserian injection of glycerol through a spinal needle inserted percutaneously into the trigeminal cistern has been shown to be an additional effective method of treating tic douloureux. The procedure is done with the patient awake under local anesthesia, and it is generally well tolerated. Pain relief from this procedure does not depend on producing sensory loss and there seems to be less likelihood of troublesome facial dysethesias. Rare complications include corneal anesthesia and keratitis. More than two thirds of patients can expect pain relief for six years or longer and the procedure can be easily repeated in the event of pain recurrence. Experimental studies seem to indicate that the therapeutic effectiveness of glycerol in the treatment of tic douloureux is based on its nonspecific neurolytic effect, which may interfere with abnormal impulse generation within the nerve. Glycerol gangliolysis may represent a major advance in the treatment of tic douloureux because it is easily done, well tolerated by patients and produces much less facial numbness than other available neurodestructive procedures.

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Migrainous Stroke—New Therapeutic Considerations

Migraine is a common disorder, present in about 5% to 10% of the general population. The clinical spectrum of migraine varies widely, from patients with infrequent mild head pains to the unfortunate group with incapacitating pain. When the neurologic features of a migrainous episode, classically thought to result from vasospasm, dominate the clinical presentation, the term "complicated migraine" is used. In some patients with complicated migraine, the vasospasm is apparently so severe or prolonged, or both, that brain tissue in the distribution of the involved vessel suffers irreversible ischemic damage, evident clinically as stroke. Aggressive migraine prophylaxis is obviously indicated in this relatively small population of patients.

Several recent clinical studies have indicated that treatment with a calcium channel blocker (specifically, verapamil) may be useful in migraine prophylaxis for patients in whom more conventional agents fail. This class of agents may prevent migraine and, in particular, its vasospastic complications, both by inhibiting vascular smooth muscle contraction and by direct antiplatelet effects. Such actions would be especially desirable for patients at risk for migrainous stroke. Propranolol hydrocholoride, however, a drug widely used for migrain prophylaxis, may actually precipitate or prolong vasospasm through potentiation of adrenergic agonist vasoconstriction.

In patients considered at risk for migrainous stroke—specifically, those in whom the neurologic accompaniment is pronounced or persistent—ergot therapy is to be avoided. Propranolol may also prove unsuitable. Verapamil, in a dose of 80 mg three or four times a day, should be strongly considered for these patients. Other calcium channel blockers such as nifedipine may possibly be more effective, but verification is lacking at this time.

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When to Stop Anticonvulsant Therapy

Because of potential side effects from long-term therapy, anticonvulsant therapy should be discontinued in patients with epilepsy as soon as there is a reasonable certainty that seizures will not recur. In practice, defining the point at which this reasonable certainty exists is a difficult question. More information is available for children than for adults. Studies of large numbers of children, with long follow-up, consistently show that about a quarter of patients who are seizure-free for four years while receiving anticonvulsant medication will relapse when the medication is withdrawn. Adults probably have a greater chance of relapse, though the precise relapse rate is not known.

There are clinical and electroencephalographic features that can identify patients who have a greater than average probability of relapse. Patients whose epilepsy took more than five years to control and those with intellectual impairment or other static neurologic abnormalities have relapses more than half the time. The presence of focal or mixed seizure disorders or the occurrence of unequivocally epilepti-form abnormalities on an electroencephalogram predict a high relapse rate.

Certain forms of epilepsy have consistent clinical and electrographic features that serve to characterize them as benign epileptic "syndromes," including typical absence seizures with 3 cps spike-and-wave complexes that occur in children of normal intelligence. Similarly, children with focal motor epilepsy who have midtemporal and central spikes (the so-called benign focal epilepsy of childhood or Rolandic epilepsy) should be considered to have a much lower than average relapse rate. Patients with these epileptic syndromes whose seizures have been controlled for four years should be considered for withdrawal of anticonvulsant therapy.

Certain potentially reversible illnesses may include recurrent seizures as part of their course. For example, metabolic derangements such as nonketotic hyperglycemia and profound hyponatremia may lead to frequent seizures that are difficult to control. Patients with alcoholism may have withdrawal seizures. None of these patients would be considered to have epilepsy, and anticonvulsant medication should be withdrawn when the underlying illness has resolved.

It appears reasonable to attempt withdrawing anticonvulsant therapy from patients, particularly children, whose epilepsy was easily controlled, who have been seizure-free for four years, who have at least average intelligence and normal neurologic function and whose electroencephalogram shows no abnormalities. This approach can be expected to yield the lowest incidence of relapse following withdrawal of medication.

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Neurologic Manifestation of AIDS

The acquired immunodeficiency syndrome (AIDS) may be complicated by neurologic dysfunction in 30% to 40% of cases. Neuropathologic abnormalities, however, are found in about 70%; this may reflect the fact that subtle neurologic signs and symptoms may be overlooked in patients with severe systemic illnesses. In about 10% of patients with AIDS, the neurologic syndrome is the initial clinical manifestation. In such cases, herpes zoster radiculitis and aseptic meningitis are the most common harbingers.

Paralleling the nonneurologic effects of AIDS, the neurologic manifestations are most often due to opportunistic infections or malignancy. Meningoencephalitis, which may be acute or chronic, is the most common neurologic syndrome. In nearly 100 reported cases, most with brain abscess formation, *Toxoplasma gondii* has been implicated. About 60 cases of probable viral encephalitis have been reported, and although the specific virus has not always been discerned, both cytomegalovirus and herpes simplex virus have been cultured from the brains of such patients. *Cryptococcus neoformans* meningoencephalitis is third in frequency, with 33 cases reported. Less frequently implicated are other fungi, mycobacteria and spirochetes. Progressive multifocal leukoencephalopathy has also been reported.

Neoplastic involvement of the nervous system has been reported in 26 instances, including cases of primary brain lymphoma, metastatic lymphoma, meningeal lymphomatosis, epidural spinal cord compression and metastatic Kaposi's sarcoma.

Cerebrovascular complications, associated with nonbacterial thrombotic endocarditis, neoplasm and thrombocytopenia, have been reported in nine cases.

Peripheral nervous system complications occur less often (51 cases). These include chronic inflammatory polyneuropathy, distal symmetric neuropathy, cranial neuropathies due to lymphoma or inflammation, herpes zoster radiculitis and polymyositis.

Algorithms have been published for evaluating AIDS cases in which there are nervous system complications. Several caveats are noteworthy: first, toxoplasmosis is not ruled out by a negative computed tomographic scan or by "nondiagnostic" titers. Second, a cryptococcal antigen test may be positive in acellular spinal fluid. Third, herpes simplex encephalitis may be atypical in course and anatomic distribution in patients with AIDS. Last, different brain abscesses in the same patient may be due to different organisms.

Treatment is outlined by Snider and co-workers and Levy and colleagues. Frequent infectious recurrences, especially with *Toxoplasma* and *Cryptococcus*, raise questions about the duration of therapy.

Unfortunately, the overall prognosis is very poor in a patient with AIDS, with or without nervous system dysfunction. However, the nervous system complications themselves are frequently rapidly fatal if not diagnosed and treated; thus, such treatment may improve both quality and quantity of life in a patient who has AIDS.

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Medical Ethical Issues

Modern resuscitative techniques, including ventilator suport, often produce ethical dilemmas in treatment decisions for patients with two types of severe brain damage: brain death, in which the patient shows a complete loss of all brain functions, both cerebral hemisphere and brain stem; and states of permanent unconsciousness. One example of the latter is a persistent vegetative state in which deep coma evolves over a few days or several weeks into a condition of eyes-open unresponsiveness and sleep-wake cycles. Physicians and patients' families are increasingly questioning the indeterminate use of life-sustaining techniques for patients who are brain dead or who are extremely unlikely to return to cognitive, sapient life. The first group of patients is, by definition, medically and (but for a pronouncement) legally dead in most American states; the second group is very much alive and must be recognized as such.

The 1981 *President's Commission Criteria,* now the nationally accepted and most current standard for the clinical determination of brain death, superseded the 1968 *Harvard Criteria.* Neurologists (or, when appropriate, neurosurgeons) should be consulted to confrim the diagnosis because conditions that mimic brain death but are often reversible—such as drug and metabolic intoxication, hypothermia and shock—may exist. Once physicians have made a careful determination of brain death, they should discuss the concept with the patient's family and explore the possibility of organ donation, if clinically feasible and otherwise appropriate. After a patient has been pronounced dead, removing the ventilator has no greater ethical or legal significance than stopping any other treatment for a dead patient.

Permanently unconscious patients present a different problem. Legal concerns added to the inherent limitations of neurologic prognoses frequently make physicians hesitate to classify patients as permanently unconscious. After a sufficient period of observation and adequate clinical evaluation, a physician's confidence in the diagnosis of permanent unconsciousness may lead to a favorable response when the patient's family or surrogate (a legally recognized representative of the patient) requests the withdrawal of treatment, thus allowing the patient to die.

These requests create an ethical issue. In 1981, both the Judicial Council of the American Medical Association and the Los Angeles County Medical Association—supported by the Council of the California Medical Association—endorsed the ethical propriety of withdrawing ventilator support from patients in an "irreversible coma" (a state of permanent unconsciousness), so long as the family concurred and the patient had expressed no contrary wish before the neurologic crisis. In 1983, a Presidential Commission urged that patients' families be recognized as primary decision makers in such cases, stating that "the law does not and should not require any particular therapies to be applied or continued, with the exception of basic nursing care that is needed to ensure dignified and respectful treatment of the patient." In addition, a California appellate court dismissed criminal charges against two physicians in a 1983 case involving the discontinuance of both ventilator and fluid support for a deeply comatose patient. The court held that a physician has no duty to continue treatment that will not improve a patient's prognosis for recovery, that has become futile and that offers no reasonable medical benefit to the patient in terms of a return to a "normal, functioning, integrated existence."

Antibiotics, blood products, cardiac drugs, dialysis, pressor agents and ventilators all might be used as life-sustaining treatment for permanently unconscious patients. No logical distinction can be made among these modalities for such patients. When the family or surrogate concurs and when the decision does not conflict with the values of the patient, physicians may ethically withhold or withdraw all such forms of life-sustaining treatment. There is a caution, however. The provision of fluids and nutrition holds a deep emotional and symbolic significance for many professionals and lay persons, who see it as one element of "basic care" for such patients. To withdraw food and fluids may generate extreme controversy and even lead to sanctions.

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Interventional Neuroradiology

Interventional neuroradiology has recently become an accepted treatment method for selected cases of brain and head vascular abnormalities. Treatment is carried out endovascularly, generally through an angiography catheter, and may be divided into two basic types: the opening of arteries that are too narrow and the closing of blood vessels that supply hypervascular abnormalities (arteriovenous malformations, ateriovenous fistulae and vascular neoplasms).

Unlike other areas of the body, the end organ (the brain), is unforgiving of careless technique. Introducing either atheromatous or inappropriately placed iatrogenic emboli into its circulation has grave consequences.

Starving hypervascular lesions of the brain and scalp is done by introducing small foreign particles—usually polyvinyl alcohol foam sponge particles, Gelfoam particles or silicone spheres—selectively into the arteries supplying the lesion through percutaneously placed angiography catheters. For ateriovenous malformations of the brain, one depends on the high flow into the lesion to carry the emboli to the correct place. Introducing tissue adhesives via selective intracranial catheterization may also be undertaken, but it is still considered an experimental procedure and is reserved for life-threatening situations. The goal is to control headache, reduce steal symptoms and lessen the likelihood of second or subsequent hemorrhage (this latter point has not been definitely proved and is controversial). Treating scalp arteriovenous malformations is significantly less difficult and is also safer than treating intracranial arteriovenous malformations. One may catheterize the external branches of the carotid artery and, by using direct fluoroscopic real-time visualization of the embolic process, may completely occlude the blood supply to these lesions. A knowledge of the anatomy of the blood supply of the cranial nerves is essential for maximal patient safety. Though meningiomas may be controlled surgically, there appears to be some advantage in preoperative embolization five to seven days before an operation to allow peritumoral edema to regress before the operative intervention.

It is particularly satisfying for a therapist to encounter a traumatic carotid artery to cavernous sinus fistula, as embolic results are excellent. The therapist may guide a small detachable balloon-tipped catheter into the cavernous sinus and then, using real-time fluroscopic control, gradually inflate the balloon until flow through the fistula has been stopped. The goal of the treatment is to preserve the internal carotid artery. Acceptance of this procedure is now widespread, and few operative approaches are thus done for traumatic arteriovenous fistulae. One expects the development of third, fourth and sixth nerve pareses in from 20% to 30% of patients; the paresis resolves over the course of three to six months.

Grüntzig balloon dilatation of atheromatous vessels has been recently reported as treatment for narrowing of the proximal brachiocephalic and vertebral arteries. Relatively few reports detail dilatation of the more common narrowing of the internal carotid artery bifurcation. Physicians doing this procedure note the importance of identifying and excluding from treatment patients who have ulcerated plaques. Special precautions are taken to decrease the likelihood of downstream embolization. Follow-up for this procedure is short but the early results are promising.

Patients are prepared for embolic procedures with steroids; the steroid dosages are tapered over the three days following the procedure. The advantage of embolic techniques is a considerable reduction in costs. Patients leave the hospital on the second or third post-treatment day. Complications of embolic and dilatation procedures appear to be similar in quality and rate to the surgical approach for these diseases.

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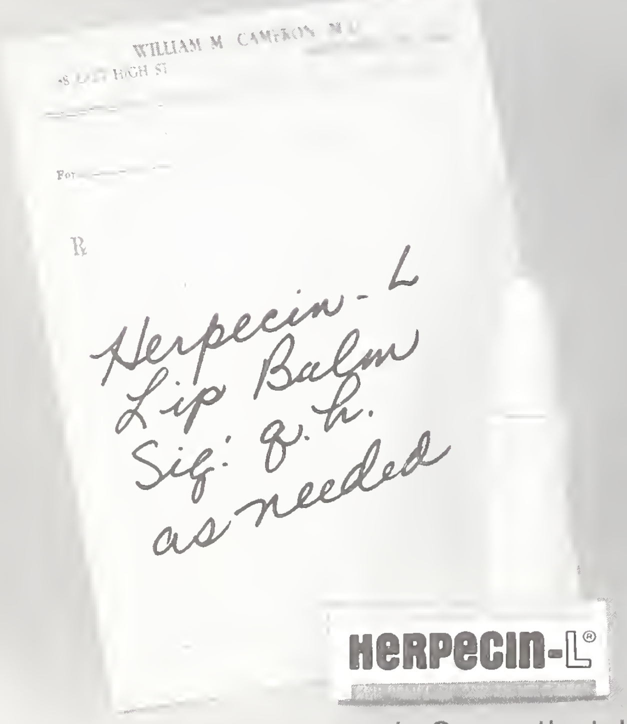

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Psychosocial Approaches to the Treatment and Management of Schizophrenics

STEPHEN FLECK, M.D.

ABSTRACT—This paper presents an overview of the author's concepts and therapeutic experiences with schizophrenia. A general systems approach is offered for the understanding of schizophrenics and their families, and consequently for multiple focus of treatment. The latter require a quasi-familial therapeutic ambience and guidance, both on in-patient and community services.

Appropriate protective and medical care, and facilitation of personal growth and personality changes as indicated are emphasized. The inadequacies of current facilities and services are stressed as a source of "chronicity" which often could be prevented by adequate and encompassing care. Neither hospitals nor community services have failed as such, but their inadequacies are the result of resource-shortages, not a lack of know-how. Procuring the necessary funds for adequate services is a political task, and physicians should be advocates in this matter and not alibi-providers for the political priority-setters with promises or hopes for cheaper, more cost-effective and "specific" remedies for any chronic illness.

Schizophrenia began its career in medical practice and literature as Dementia praecox, that is by definition a condition with a downhill course of deterioration. A century later we are still contaminated by this original definition of schizophrenic disorders despite ample evidence that this condition need not, indeed, does not usually result in any organic brain impairment in terms of known brain functions, and the well-documented evidence that the clinical course is not only intermittent in most cases, but by no means invariably a downhill course in terms of mental functions, behaviors and social adaptation.[1,2]

Chronic illness means that no etiological factor without which the condition could not arise has been discovered, and that empirically no treatment that might neutralize or eradicate such a factor, even if unknown, has been discovered either. In this respect, schizophrenia is liky hypertension or collagen diseases, and even diabetes for which despite the availability of a specific substitute for over half a century, no basic sine-qua-non factor or factors have been discovered or even stemmed completely by the treatment. Like such chronic diseases, schizophrenia also is the source of enormous disability, and ranks second only to arthritis in this respect. Yet, as the term "chronic" itself implies, one can live a long time with these conditions and despite the high prevalence of disability caused by them, many such patients lead productive and some even satisfactory lives for many decades. These similarities are important to emphasize because on the one hand it is usually alleged and even assumed that we psychiatrists are coping less well, and that our clinical work is less exact than that of our colleagues in other specialties, which is not necessarily so, and secondly, because among ourselves we seem prone to emphasize our uncertainty and lack of knowledge—*"the underlying cause of schizophrenia is unknown"*—when in fact we know a good deal about what at least contributes to the development of schizophrenia, maybe more than we know about what contributes to the development of arthritis or cancer. However, only in psychiatry or the Mental Health field does the word chronic also denote poverty and social ineffectiveness.

Finding sine-qua-non factors is obviously important because without them specific prevention will not become possible, but even the discovery of a sine-qua-non etiological factor does not necessarily result in the preventive technology to eliminate such a factor, or substitute for it, if it turned out to be a deficiency. The tubercle bacillus was identified about the same time that Kraepelin established the clinical entity of Dementia praecox,[3,4] but we still have to find an im-

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Presented in part at the Greater Bridgeport Community Mental Health Center Symposium on the care and treatment of the chronic schizophrenics, towards the end of the century: "Better or Worst," on October 25, 1985.

munizing measure against tuberculosis which is specific and safe, rather than general preventive measures like adequate nutrition or pasteurization of milk. But the fact that the incidence of tuberculosis has been vastly reduced in the more developed countries by counteracting contributory factors such as malnutrition, raises hope that the prevalence of schizophrenia also can be reduced by addressing and eliminating certain contributory factors which we do know. It is clear, however, because of the worldwide estimated incidence of schizophrenia, which has not changed much for as long as we have estimates, that improvement in general living standards, nutrition or education have not affected the incidence of schizophrenics.[5] Yet we also know that socio-economic and cultural disadvantages are significantly and positively related to the prevalence of schizophrenia, that is, they promote or contribute to chronicity as noted above.[6]

Schizophrenia is a profound personality disturbance characterized in its acute presentation by deficient self-boundaries, by aberrant cognition and symbol usage, concrete thought patterns, intense anxiety and usually a history of relationship and communication difficulties, which however often remain rather subjective or covert until the time of the first overt psychotic break. Interpersonal activity is severely embarrassed by these aberrations and by schizophrenics' egocentric and concrete communication modes.[7,8] It is not necessary to present in detail the many manifestations which can result from the inchoate depths of this profound personality disturbance, whether one elaborates on Bleuler's four cardinal processes or makes phenomenological sub-divisions according to particular symptoms and behaviors as Kraeplin did, or whether one agrees or not with the current research diagnostic criteria reflected also in DSM-III,[9] the personality malformations I have indicated will be there if the diagnosis of schizophrenia is to be sustained. For instance, one can have a very constricted sense of self and not be schizophrenic. But if one has a defective sense of self and fails to distinguish what's inside and outside after the age of 3 or 4, it is difficult to imagine how one can eventually be other than schizophrenic. I venture, therefore, that schizophrenia is a developmental disorder, a deficiency disorder in that certain human attributes, among them a sturdy sense of self and one's roles in family and community must be attained in order to function as a person, to work and love, as the currently popular standard for mental health has it.

That such significant deficiencies in the sense of self, in ego boundaries and in one's cognitive and symbolic operations can be the result of some deviant brain chemistry can well be imagined, but that remains speculation. It does not, however, require much imagination to assume confidently that different thoughts and different ways of thinking also entail differences in cellular and intercellular electro-chemical processes; but until we have them in hand, i.e., understand the chemistry or electrical patterns of thinking in more discrete microbiological terms than the EEG or the neuroendocrine processes we can identify with our current assay competence, the biological components of schizophrenic aberrations remain an area for investigation; utilizing also those chemicals which have been found empirically to reduce or alter schizophrenic symptoms.

In the meantime, as clinicians we ought to attend primarily to those phenomena which we do understand in terms of their psychological and interactional meanings, and about whose development we have relevant information. We know that the personality defects of schizophrenic persons do not occur randomly, but develop as all humans do in the context of a family. We know that regardless of what physiochemical diathesis there may be, the earliest mother/infant interactions produce psycho-physiological consequences which vary with the nature of bonding behaviors. We also know that mothers of young, later schizophrenics are often handicapped in this earliest nurturant phase. However, this deficiency is only one of many discovered in recent decades in the capacity of such families to function wholesomely. I shall return to this familial aspect of schizophrenic development presently, but aim to emphasize first that because of the psychosocial vicissitudes in the backgrounds of schizophrenics and their related psychological pathology and interpersonal incompetences, these patients need psychotherapeutic treatments and sociotherapeutic measures for their restitution and rehabilitation or even habilitation. This will remain so, no matter what chromosomal aberrations, or what better and more specific chemotherapies we may discover, unless prevention can obviate treatment of any kind.

In contrast to the relatively technical measures like chemotherapy or social guidance, dyadic psychotherapy is the use of self—all of one's self—on behalf of another person. This includes those aspects of one's person with which one would rather not be acquainted. In psychotherapeutic work with schizophrenics in particular, attention to these more archaic facets within ourselves may be as important as our cognitive selves; specificially our knowledge of theories or facts about personality development and structure, about the biology of schizophrenia and the chemistry of neurotransmitter systems.[10,11]

Moreover, thanks to the investigations of the last thirty years we can now include another important dimension—a kind of fourth ear—for our inner mental workings and our conceptualization and understanding of schizophrenics' bizarre and obfuscating behaviors. The first three ears attend, of course, respectively to the biological, the biographical or psychosocial and the unconscious levels of an interviewee. The fourth ear attends to what we have learned about the familial roots of personality development and structure which, in the case of the families of schizophrenics, are often as bizarre and confusing as the patient's behavior and language.[7]

In order to appreciate the striking differences between the functioning of families with a schizophrenic offspring and others we need to understand what families are about and for the world over, which is (1) to generate, protect and nurture the very young; (2) to prepare children through enculturation and formal education where required for adulthood and meaningful and productive participation in their society and, (3) to tend to their own operations as special small groups. But the parents of schizophrenics as persons are often handicapped by significant abnormalities of their own. One or the other may show a borderline organization or even be psychotic, and the marital coalition that evolves in such situations may be deficient in properly effecting the evolving triangular relationships when children arrive. We have distinguished between schismatic and skewed relationships; the first, in which there is strife between, and mutual undermining by, the parents, and the second, a situation where one spouse submits to the other, usually the more disturbed one whose aberrant views and behaviors then dominate the family atmosphere, protecting the marriage at the expense of family tasks.[7]

It is, therefore, essential to examine and evaluate a family not only cross-sectionally, but also longitudinally and historically, ideally over more than the nuclear two-generational span. Although a family interview may reveal significant family pathology, especially by analyzing intra-familial communication, we also need to understand the development of the difficulties. Unlike the testing of an organ or physiological system, where the fact of prior adequate liver function in a now jaundiced patient, for instance, does not put into question the development or structure of that organ, but most likely would make us search for a very recent noxious agent within or beyond the liver, family pathology, like psychopathology, does not arise de novo, but is always embedded in antecedent events or processes in that same system, including the genetic endowment.

We have proposed to examine the family as a system through a five-pronged approach. These five parameters are: leadership, boundaries, affectivity, communication and task and goal fulfillment through the life cycle stages (Table 1). Topical statements about these five system elements with their twenty-eight subheadings, based upon the family history and direct observations can be accomplished and summarized in a grid which also can be used for quantitative assessments (Figure 1).

The leadership deficiencies in families with a schizophrenic offspring have already been indicated above. Ego boundaries may be defective in one or the other parent and the development of children's ego boundaries is often embarrassed by parental intrusiveness or engulfing behavior. In families where a parent/child dyad becomes dominant instead of the parental coalition, the generation boundary is violated, thereby often perpetuating incestuous proclivities. The defective family/community boundary was first described by Wynne and his associates as a "rubber fence" in that no family member is really allowed to leave the group and sometimes this impermeability is fostered by a paranoid stance toward outsiders. Bowen stressed the undifferentiated "family ego mass."[12,13]

Table 1

Leadership	*Boundaries*	*Affectivity*	*Communication*	*Task/Goal Performance*
Parental personalities	Ego boundary development in children	Inter-parental intimacy	Responsiveness	Nurturance and weaning
Marital coalition	Generation boundary	Equivalence of family triads	Verbal/non-verbal consistency	Separation mastery and family triangles
Parental role complementarities	Family-community permeability	Tolerance for feelings	Expressivity	Behavior control and guidance
Use of power (discipline)		Unit emotionality	Clarity as to form and syntax	Peer relationship management
			Abstract and metaphorical thinking	Unit leisure
				Crisis coping
				Emancipation
				Post-nuclear family adjustments

Figure 1

INTERACTIONAL - HISTORICAL SYSTEMS GRID FOR FAMILY EVALUATION

	0	*1*	*2*	*3*	*4*	*5*
	Not rated	*Adequate or better*	*Somewhat deficient*	*Moderately deficient*	*Aberrant*	*Grossly aberrant*
Leadership 1. Parental personalities 2. Parents' emancipation 3. Mutual support (+ coalition) 4. Power use + discipline						
Boundary Management 1. Mother-child dyad 2. Separation coping (ego boundary) 3. Generation boundary (intrusiveness?) 4. Family-community passages (rigidity vs. looseness; "rubber fence")						
Affectivity 1. Age-appropriate intimacy 2. Equivalency of family triads (e.g. scapegoating) 3. Tolerance for feelings 4. Unit emotionality (celebration or mourning)						
Communication 1. Clarity and respect for boundaries (speaking for oneself) 2. Confirmation and support (empathy) 3. Content responsiveness 4. Affect responsiveness 5. Verbal/non-verbal consistencies 6. Syntax 7. Contents (thought disorders, etc.) 8. Abstraction						
Task Fulfillment 1. Parental role complementarity 2. Nurturance and weaning (attachment-separation) 3. Enculturation 4. Peer relationship management 5. Unit leisure 6. Emancipation 7. Crisis Coping 8. Tangible tasks & distribution						

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As to affectivity the parents may be overly intimate and involved with each other at the expense of parental functioning, or, as already indicated, they live in chronic strife and conflict which also distorts family functioning. It is usually only one child who is over-involved with one or both parents, thus establishing an unequality among the respective basic family triads. There may be intolerance for feelings and these may be mislabeled and distorted, as emphasized in particular by Hilde Bruch.[14]

The abnormal and bizarre ways of communicating on the part of schizophrenic patients have long been observed and studied, but the familial aberrations in communication have been outlined in detail only in the last twenty-five years, especially through the studies of Singer and Wynne.[8] The intrafamilial communication may be unclear, vague or completely amorphous; responsiveness is inconsistent as is simultaneous verbal and non-verbal interaction. Communication often shows the double-bind feature first elaborated by Bateson, Jackson et al.[15] On a more basic level categorization and abstract thinking essential to inter-human understanding, as pointed out by Piaget,[16] are usually defective in these families.[7]

Instead of emancipation of the younger person, at least on an emotional plane, one of the basic family missions, the family remains over-involved with a schizophrenic member. Middle-age or older age parents fail to return to dyadic living, characteristic of industrial societies, but such patients cannot manage life on their own. Even if the parents wanted to eject or reject the disappointing offspring, deinstitutionalization has by and large foreclosed that option. They must adapt themselves to the chronic disabilities of their schizophrenic offspring, who often lead a marginal or institutional existence, even if apart from their families of origin. Vaughan, Leff, Brown and others in England[17] have accumulated important data indicating that recovered schizophrenics, usually on maintenance medication, may do better or may do worse by living with their families. Patients whose families can accept them, having learned to tolerate his or her difficulties and limitations, do better at home particularly if their social skills and capabilities remain low as they often do. However, with families where there is continued expression of disappointment and frustration about the patient's misfortune, the latter is better off not living with the family, although continued contact remains essential. These findings are consistent with our own follow-up studies and those of Goldstein in California.[18] The particular group of patients we studied most intensively, offspring of affluent and educationally ambitious families, were usually better off not to return to their families because of the psychosocial achievement expectations in such upper-class environments. This is not the case in many other socio-economic groups or other cultures where unmarried adults rather usually live with their families of origin or some collateral.

What needs particular emphasis at this time is that humanely, but not necessarily intensively-treated schizophrenics were able to recover and have lead reasonably satisfactory lives with their families or others, long before modern drugs or even insulin or electroshock became available. This is borne out by longitudinal studies in Switzerland, in Finland and in West Germany,[1,19,20] and by the recent Vermont study by Harding and Strauss,[2] and also was the experience of the Phipps Clinic at Johns Hopkins and the Boston Psychopathic Hospital long before neuroleptics became available.[21] These data do not constitute a contra-indication to the employment of biological and pharmacological measures which have been extremely important in shortening states of excitement, of total withdrawal, of combative phases, behaviors that often render these patients inaccessible for psychotherapeutic work and sociotherapy for a period of time. But those earlier experiences also indicate that drugs alone, or for that matter, insulin, or wetpacks, are not *the* treatment anymore than are psychotherapy or family treatment by themselves. (Such claims advocating a singular treatment form are not uncommon by either pharmacomegalo-therapists or psychomegalo-therapists.) All of them—biological measures, family- and group-therapies, and dyadic treatment are essential in the recovery and restitution of schizophrenics (Table 2), and should be routine measures with acute schizophrenics, especially for those in their first break. They should be treated in their community on general hospital psychiatric services, or a community mental health center. Such a service or ward should consist of 20 to 30 patients, not necessarily all schizophrenic, and these patients should participate in therapeutic community programs, group meetings and patient-government. Their families also should be involved with the ward programs.[22] Beyond these, there must be opportunities for gradual integration into the community, i.e., programs of partial hospitalization, half-way houses, sheltered apartments and workshops and rehabilitation groups.

Dr. Stanley Possick and I have elsewhere addressed in detail the similarities and differences in family and

Table 2
SCHIZOPHRENICS DISABILITIES AND NON-PHARMACEUTICAL TREATMENT NEEDS

Life Tasks	*Symptoms of Failure*	*Corrective Treatment Modes*	*Relevant M.H. Experts*
1. Self-preservation	Personal neglect suicidality	Nursing care medicaton	RN, MD
2. Self - non-self management	Aloofness, tactlessness, violence	Same and behavioral techniques	RN, Behavior Specialist
3. Actual or eidetic harmony in and with family of origin	Disharmony, rudeness, abrasiveness, overcloseness	Psycho- and family therapy	Individual and family therapists
4. School or work	Inability to work, or study or sustain oneself independently	Work therapy and rehabilitation or school	Special school or occupational therapist
5. Recreation	Anxiety, avoidance possible bizarre diversions	Recreation and activity therapies	Activity and recreation specialist
6. Friendships	Avoidance and feeling of being observed by others	Psycho- and group therapy	Milieu and leaders sociotherapy (in groups)
7. Intimacy with Significant other	Shallow relationships if any and may exhibit delusional "friends"	Same	Psychotherapists

Modified from Stone, MH: Integration of Theory and Therapy in Stone, MH, Albert HD, et al (Eds) Treating Schizophrenic Patients. McGraw-Hill Co, New York, 1982.

therapeutic systems.[22] The similarities were noted two centuries ago by Samuel Tuke,[23] one of the pioneers of the human asylums, and again fifty years ago by Simmel[24] who established the first psychoanalytic hospital. Although no longer infants our patients often need total care as well as a graduated hierarchy of weaning steps toward increasingly independent functioning. However, this gradual movement toward self-sufficiency cannot stop or be finished at the ward door when the patient leaves, no matter how ideal and effective that therapeutic community may be. Similar nurturance and guidance—holding and facilitation—must continue in out-patient and community settings. Besides the aforementioned agency types further work with patients' families is necessary whether the patient returns to live with them or not. We must go beyond the assessments of high or low emotionality. These families who should be involved with the therapeutic work on wards need to continue thus after the patient's discharge; not only to ascertain that their interaction with their schizophrenic member continues beneficially, but also because they are, but must not continue indefinitely, in a state of mourning as emphasized by Chalk[25] and Bahnsen.[26] The reality of a chronically disturbed or deficient close relative can usually not be accepted and mastered without professional help or treatment. This does not mean telling them as is advocated by some, that the patient will always be schizophrenic, but dealing with and healing parental disappointment and guilt, and even that of siblings. This is our job even as we must advise limited expectations for a time, and maybe a long time being. This task like that of psychotherapy with schizophrenics is arduous, and often discouraging, but it is our job not be infected by the family's distress, by their guilt or even despair.[27] Nor should we accept or communicate Kraeplin's pessimistic contention reflected in his term Dementia Praecox, even when camouflaged as in DSM III.[9]

Leadership or governance in mental health agencies need be shared as it is on our in-patient services, without the director(s) abdicating ultimate responsibility. This is similar in families in modern societies where parental role-complimentarily and effective communication are essential for wholesome family functioning. Sharing responsibility and decision making is also essential between agencies or services involved with a particular patient. The so-called referral of a patient for additional simultaneous treatment or a related program is an exercise in futility unless there is also mutual systems involvement in all parameters beginning with shared treatment planning. Besides psychiatric services these patients eventually need half-way houses, protected living quarters, schooling or rehabilitation, and gradual transition into the work force. Like toddlers in their distancing—reapproachment experiments our schizophrenic patients often improve in zig-zag fashion—moving out and then needing another period of more care and protection. Agencies therefore must be prepared to collaborate flexibly, and arrange for intermittent increased care.

Obviously our society falls woefully short in providing the integrated spectrum of services outlined here, and we continue with rather apathetic attitudes and policies towards these patients and their families, which was first engendered by the thesis that until THE cause is discovered we cannot treat such patients effectively, let alone specifically. THE cause may be discovered some day in that we may find a neurobiological weakness or aberration without which one cannot become schizophrenic, whether such an X is inherited or not; but, as with other chronic illnesses, eradicating or compensating for THE cause, as we do with insulin for diabetics or streptomycin for tubercular patients respectively, is insufficient treatment. There has to be continued attention to such patients' eating behavior or their exposure to noxious inhalants, their exercise patterns etc. and the same will be true of schizophrenics where we have to help with their attitudinal and social behaviors, and their reintegration into families and community. And, as is the case at the beginning of life as well as throughout, the first and usually most significant psychosocial system, whether beneficial or detracting, is the family, often also the major so-called health care provider.[28]

Here we have the opportunities for what may euphemistically be called primary prevention i.e. improvement of family life in general through appropriate education concerning reproduction, child spacing and the nature of family tasks through the life cycle. Regardless of any genetic or biological deficits new-borns may bring with them, appropriate and compensatory rearing in a caring and well-functioning family would go a long way in neutralizing whatever diathesis toward schizophrenic maldevelopment might exist at birth.

However there is another preventive aspect which can be accomplished more readily, and that is preventing chronicity in from 2/3 to 3/4 of schizophrenic patients by the measures I have outlined. That we fail to do that is the real shame of our field—not only of mental hospitals.

We have failed in the political arena to influence our legislators to provide the funds for comprehensive care. This reflects of course the public's attitude of indifference, if not hostility, toward mental patients. But it also reflects our own preference for simplicity and straight cause-and-effect paradigms. This often is called the medical model, but it is a model based on fantasy. Peabody[29] pointed out (and I paraphrase) that establishing a diagnosis should be maximally scientific, but that the care of the patient lies in caring for the patient. That was six decades ago. But clinical care will never come cut-rate, and Lewis Thomas' claim that health care expenses will be reduced by appropriate technological discoveries and advances doesn't fit the facts.[30] He points to poliovaccine which is not only preventive, but also has saved us the expenses of treating poliomyelitis. That's obviously so, but renal dialysis and transplants, equally life saving or preventive of disability have become an enormous expense, certainly greater than letting our uremic patients die peacefully. Thus better and even specific treatment may or may not save money. It is disgraceful for our profession to hold out promises of "cost-effectiveness" through brief treatments for prolonged illnesses, or as Dr. David Hunter[31] put it recently: "To say that long-term intensive family therapy [and other forms] is too expensive, is to say nothing more than that social planners and financial managers would rather allocate society's resources elsewhere. That they can count on a subgroup of clinical researchers to justify their priorities is not surprising, merely a pity." I would add: it's disgraceful. We have often oversold programs due to enthusiasm and uncritical acceptance of a particular remedy, but becoming the handmaiden of thinly veiled efforts to curb and reduce adequate clinical care is new for us. Community mental health care is not and cannot be cheaper than institutional care, let alone inadequately financed institutional care, although it has shifted some of the expense from the H to the HS in our Health and Human Services departments. Deinstitutionalization is a principle which has not failed. It has failed in practice because we have not provided the wherewithal, because our public hospitals often cannot treat inpatients properly and long enough, and the essential establishment of a care-network in the communities has not occurred for the most part. State Mental Health departments get the blame and carry the brunt of poor clinical practices: overmedication and under-socialization in hospitals, and community services with inadequate resources. Fitting patients to our fragmented programs is one of our major sins instead of providing integrated programs suited to our patient's needs. Blaming the "bureaucrats" for such deficiencies is like blaming the messenger, an ancient ploy to avoid responsibility; appointed officials carry out legislative mandates which reflects compromises among voters, politicians and professionals.

To repeat we know how to treat schizophrenics much more effectively than we do for the most part. We can restore the majority to useful lives, given the proper resources—manpower-intensive resources—and we have learned how to work as systems, as teams, as no other medical specialty has so far done. We could prevent chronicity in most schizophrenic patients, and also provide a model for comprehensive care for all chronic illness. As Dr. Leon Eisenberg put it: "Psychiatry at its best is a paradigm for the general medical practice of the future. This may seem an outlandish claim for a field which boasts of so few spectacular advances. Yet I believe it to be true because psychiatric practice deals with human distress in a context which must include the psychosocial as well as the biological. There are no imperialistic aims behind this claim. Quite to the contrary, in so far as psychiatry is successful in clarifying the psychobiological and social bases of health and illness, that knowledge will pass into the domain of the generalist and the psychiatrist will join other specialists in the secondary and tertiary cadres of the health system."[32]

I would reiterate that our quasi-familial modes of work in mental hospitals and in the community, working as multidisciplinary teams is a model for the care of all patients with prolonged illness or disabilities. We know how; to get the job done requires a much more active political advocacy from us, instead of passively accommodating to political efforts to save money at the expense of our patients.

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—COMPUTERS & YOUR MEDICAL PRACTICE*
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—PULMONARY REHABILITATION*
by Dr. Katherine III
—HAZARDOUS INFECTIOUS WASTE MANAGEMENT & TREATMENT*

12:45-1:45 pm
—LAUNCHING A MEDICAL PRACTICE
—DIAGNOSIS & TREATMENT OF A MEDICAL MALPRACTICE SUIT*
by Joseph Flynn
—ADULT CHILDREN OF ALCOHOLICS
—DANGERS OF SMOKING

2:00-3:00 pm
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—ALTERNATIVE HEALTH CARE DELIVERY SYSTEMS*
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3:15-4:15 pm
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Trauma in the Pregnant Patient

WARREN CROSBY, M.D.

Trauma is the leading cause of death in women under the age of 35, and pregnant women are certainly part of these statistics. Although the basis of my experience in trauma during pregnancy relates mostly to automobile trauma, the principles involved apply to trauma inflicted in any manner whatsoever.

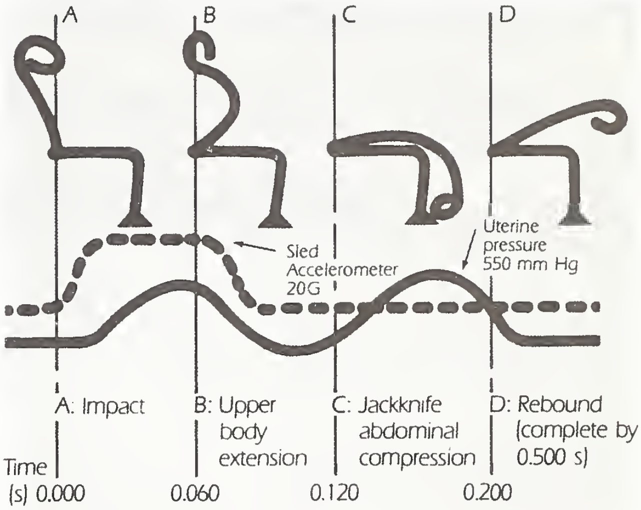
There are nearly 3.5 million births per year in the United States. Each of these pregnant women is probably subject to the same risk of accidental trauma during travel as her nonpregnant sister or her husband, but there is very little known or reported concerning the effect of such trauma when the victim is pregnant.

There have been some case reports of spectacular injuries involving accidental trauma to the pregnant woman and her fetus; however, until our work in the late 1960s, there had not been a single systematic study of automotive trauma involving pregnant women. Nor was there any solid information available to determine the wisdom of pregnant women using restraint systems while traveling in automobiles. In several states, automobile accidents continue to be the leading nonobstetric cause of maternal death. I would like to briefly summarize our studies concerning automotive injuries during pregnancy, as well as approaches to prevention and to emergency room treatment.

Investigating Seat-Belt Safety

Our initial studies began in 1965 and utilized the pregnant baboon as the experimental animal. The plan was to attempt to delineate exactly what happens to the pregnant accident victim during a head-on collision. Each automobile accident is unique, but there are general characteristics that are common to the major types of collisions.

All head-on collisions involve continuation of the forward motion of the occupant after deceleration of the vehicle, with impingement of the moving passenger on various parts of the decelerating vehicle. Similarly, rear-end collisions involve impingement on the back of the passenger against the automobile seat. Our purpose was to see what lap-belt restraint did to the pregnant experimental animal under conditions of a simulated head-on automobile collision. The pregnant baboon was placed in a scaled-down padded automobile seat on an impact sled that was then impacted at 20 × gravity—this is equivalent to a car crashing into a brick wall at approximately 35 miles per hour. The animal was lightly anesthetized.


A
B
C
D
Sled Accelerometer 20G
Uterine pressure 550 mm Hg
A: Impact
B: Upper body extension
C: Jackknife abdominal compression
D: Rebound (complete by 0.500 s)
Time (s) 0.000
0.060
0.120
0.200

Uterine pressure is elevated substantially at initial upper body extension and again at jackknifing of the body over the belt.

Figure

Impact sequence: Relationship between body motion, uterine pressure, and belt tension.

The pregnant baboons restrained by a lap belt began to move forward as the sled decelerated (see Figure 1). There was subsequently compression of the uterus, which elevated the uterine pressure to a level tenfold higher than pressures recorded during labor. (This pressure was partly compensated by an increase in intraperitoneal pressure, but in every case the intrauterine pressure exceeded the intraperitoneal pressure by more than 50%.) When forward flexion of the mother's body was prevented by the addition of a shoulder harness to the lap belt, the rise in uterine pressure was almost as high as it had been with the lap belt restraint alone. However, fetal bradycardia was less severe and of shorter duration.

None of the mothers who wore either type of restraint died as a direct result of the crash, but three of the ten mothers had significant traumatic injuries. None of the fetuses survived the experiment, and three of the ten sustained direct impact injury. We concluded that the deaths resulted from maternal shock, placental separation, or direct fetal skull injury.

The next series of experiments was designed to test

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the difference between lap-belt restraint and the three-point restraint system; the latter system has now been installed in all American and foreign cars in this country by adding the shoulder harness to the lap belt. The impact force and configuration were similar to those in the original experiment.

Twelve animals were impacted as they wore the three-point restraint (the animals were randomly assigned to the two experimental groups). There was one fetal loss; the cause of death was not apparent. None of the mothers was injured. Ten animals were impacted under similar conditions, but they wore just the lap-belt restraint. The fetal death rate in this group was 50%.

It seemed clear from this study that prevention of the mother's forward flexion through use of a three-point restraint offered the fetus greater protection during the collision than did the lap-belt restraint alone.

With these results in mind, we extended our research to the human pregnant automobile accident victim. Our study compared the accident reports of pregnant women who had worn lap belts with those who had been unrestrained at the time of the crash. Our aim was to determine whether pregnant women should utilize the lap-belt restraints that were available in the 1960 automobiles (the simple lap belt without the shoulder harness).

It was clear to us, before we began the study, that the sudden deceleration that occurs upon impact will focus more of the force of the collision on the lower abdomen if the woman is wearing a seat belt than if she is not belted. It was intuitively felt that, while the restraining action of the belt might help protect the mother from being ejected from the automobile after the collision, it would more often cause fetal injury by compression—injury that might have been avoided had the belt not been used. But this was not the case. In our study, the leading cause of fetal death was death of the mother. There was no statistically significant difference between fetal losses in surviving pregnant women who were belted compared with those who were not.

We obtained more detailed data from the California Highway Patrol, who sent us copies of automobile accident reports in which one or more of the occupants was identified as being pregnant. In these accident reports, the physical severity of the collision is based upon the extent of damage to the vehicle as estimated by the investigating officer at the scene. The names and addresses of the victims and the witnesses are recorded, as are the details of the collision.

After receipt of each report we corresponded directly with the victim or her family and asked for written permission to obtain medical information from the doctors at her hospital. Following this, the physicians who had been involved in the victim's care were contacted, and details of the accident's aftermath were combined with details of the collision. On the basis of 678 reports we received, there was enough information to include 441 pregnant accident victims in the study.

The majority of the collisions—233—were minor ones and resulted in no significant maternal injuries (Table 1). However, there were four pregnancy losses: two stillbirths that occurred within 48 hours of the collision; one stillbirth one week following the collision; and one congenitally malformed infant who died soon after delivery (which took place six weeks following the collision). It is apparent that minor collisions involving pregnant women do not often injure the mother, but are followed by perinatal loss soon after the collision in approximately 1% of the victims (Table 2). At this point, it is not possible to determine just how the trauma leads to the fetal loss.

Table 1
MATERNAL INJURY IN MINOR COLLISIONS

	Belted (41 cases)	*Not belted (197 cases)*
Death	0	0
Injury		
Rib fracture	0	2
Single fracture	0	1
Total	0	3(1.6%)

Table 2
FETAL INJURY IN MINOR COLLISION

	Belted (41 cases)	*Not belted (197 cases)*
Death	0	2(1%)
Injury	0	0

Table 3
MATERNAL INJURY IN SEVERE COLLISIONS

	Belted (28 cases)	*Not belted (180 cases)*
Cause of death		
Head injury	0	7
Internal injury	1	5
Multiple fractures	0	1
Burns	0	1
Total	1(3.6%)	14 (7.8%)
Injury among survivors	(27 cases)	(166 cases)
Multiple injuries	0	3
Multiple fractures	1	11
Internal injury alone	0	1
Single fractures	1	8
Total	2(7.4%)	23(13.9%)
Total maternal injuries	3/28 = 10.7%	37/180 = 21%

With more severe collisions, there were more serious injuries to both the mother and the fetus. There were fewer maternal deaths and injuries among those mothers who wore seat belts, but the individual differences were not statistically significant (Table 3). The most common cause of maternal death in unrestrained victims was head injury. Nearly as common were internal injuries involving chest, abdominal, and uterine contents. Among survivors, the most frequent severe injuries were multiple fractures, followed by single-extremity fractures.

As previously noted, the leading single cause of fetal death was death of the mother (Table 4). When the mother survived, premature separation of the placenta was the most frequent cause of fetal loss. One fetus was born prematurely and died of hyaline membrane disease. The number of abortions occurring in women under 13 weeks gestation was 10%—no greater than the rate for noninjured women in early pregnancy.

Table 4
FETAL LOSS IN SEVERE COLLISIONS
(PREGNANCIES OVER 12 WEEKS' GESTATION

Cause of fetal death	*Belted (24 cases)*	*Not belted (166 cases)*
Maternal death	1 (4.2%)	13(7.8%)
Maternal survivors		
Abruptio placentae	1	5
Maternal shock	0	3
Unknown cause	2	2
Hyaline membrane disease (neonatal death)	0	1
Total	3(13%)	11(7.2%)
Total fetal loss	4/24 = 16.7%	24/166 = 14.5%

Injury to occupants of automobiles occurs as a result of collision between the occupant and the interior of the vehicle. Among unrestrained victims, the most common maternal injuries seen in our study involved the head and extremities. Unless directly struck, the uterus and placenta are sometimes spared the effects of force that are absorbed by other parts of the mother's body.

In belted victims, however, the decelerative force is always directed toward the pelvis by the restraining action of the lap belt. We found that the belt reduced maternal injury by preventing ejection from the vehicle and by eliminating secondary impacts within the interior of the car. However, the amount of force directed toward the pregnant uterus when the body of the mother jackknifes over the belt often exceeds that which occurs in unrestrained victims. Conversely, ejection from the vehicle substantially increases the risk to the accident victim because the body of the victim is then subject to a much wider variety of lethal impact surfaces—the pavement, trees, fence posts, or other vehicles on the road.

Because the leading cause of fetal death is death of the mother, lap belts seemed to be preferable to no restraint at all. We concluded, "Our study provides no evidence that lap-belt restraints increase the mortality of either mother or fetus when pregnant women are victims of severe collisions. In addition, since mortality of unbelted victims is statistically related to ejection from the car, seat belts, which usually prevent such ejection, should be recommended for pregnant travelers."

As noted earlier, experiments in baboons showed that the addition of the shoulder harness to the lap-belt restraint system reduced the risk of both maternal and fetal injury by distributing the decelerative force more evenly and by preventing forward flexion. Unfortunately, less than 20% of occupants of automobiles wear seat belts! Pregnant women definitely need the protection of restraint systems—even more than nonpregnant travelers.

The American College of Obstetricians and Gynecologists is beginning a campaign to urge the wearing of seat belts, and we feel that, in your role as an obstetrician, you should help, too. One way of doing this is to have prescriptions printed and signed by the doctor that instruct the patient to "Use your seat belt."

Management Guidelines

Each trauma victim is, in a sense, unique. No one else has the same combination of injuries with the same effect. Nevertheless, certain sound guidelines in the management of the pregnant trauma victim may be suggested. Immediate priorities are the same as those for the nonpregnant victim: Bleeding must be stopped by ligature or compression and by immobilization of fractures. Immobilization of fractured extremities, vertebrae, and pelvis reduces the blood loss in the surrounding tissues, which may be extensive.

Blood replacement is mandatory in hypovolemic shock, but other fluids will be helpful if blood is not immediately available. Because blood volume is normally increased during pregnancy, blood replacement in the pregnant victim should be generous. In late pregnancy, vena caval compression may occur when the victim is supine—only obstetricians are generally aware of that. The resulting reduction in return of venous blood to the heart reduces cardiac output and maternal blood pressure. In addition, it may increase the venous pressure in the lower half of the body and produce more bleeding in the injured areas. Pregnant trauma victims should be instructed to lie on their left side in essentially all instances.

When a pregnant trauma victim arrives in the emergency room, a great deal of excitement erupts once the pregnancy is discovered. A sort of diagnostic and therapeutic paralysis sets in when the treating physicians and nurses realize that what they do to the mother might somehow harm the baby. The threat of perinatal litigation looms large.

It is mandatory for the emergency room physician to summon the patient's obstetrician or any obstetrician that might be nearby. Also, it is important that the obstetrician agree to come. Obstetricians will, generally speaking, say, "I don't know anything about trauma. I don't want to go to the emergency room." But they must go because they are the only ones who have the knowledge to protect the welfare of the fetus. They are the only ones who know about fetal monitoring, caval compression, the need for the woman to lie on her side, and so on. Their expertise is absolutely needed, and they and the trauma surgeon must work together.

The emergency room physician should carry out the usual plan of action: a quick review of the traumatic event so that the most likely sites of damage can be anticipated; a continuation of the physical examination of vital signs and search for broken bones; and the initiation of preventive measures, such as IVs and laboratory work.

The obstetrician can assist in this setting by assuming responsibility for the fetus. The obstetrician should caution, as mentioned previously, that patients in late pregnancy should be transported and generally kept on their left side rather than flat on their back. He or she should also remind the trauma surgeon that the pregnant woman has an increased blood volume, and that if blood replacement is necessary, more should be given than would normally be the case.

Another point for the obstetrician to be aware of—and to share with the emergency room physician—is that the pregnant woman maintains her vital signs for a longer period of time in the face of excessive hemorrhage than do older or nonpregnant women. In fact, the pulse rate and the blood pressure may be maintained in a normal range until just before the vascular system entirely empties itself and irretrievable shock occurs. The job of the obstetrician is to prevent this by working together with the trauma surgeon to monitor the woman's condition closely and to intervene promptly when the situation calls for it.

Another of the obstetrician's responsibilities—and one that should be performed immediately—is to obtain a fetal monitor from the nearest delivery room. Aside from the benefit to the fetus, this will also aid the mother, because the fetal heart rate may be a better monitor of the maternal condition than almost any other parameter. The fetus is, of course, extremely sensitive to decreases in maternal blood flow and oxygenation; therefore, the fetal monitor will serve as a warning of impending doom for both the fetus and the mother. Even in mid-pregnancy—when the fetus may not be an appropriate subject for an emergency cesarean section should the monitor tracing indicate impending death—the monitor can be useful in prompting earlier volume replacement or laparotomy to stop bleeding.

The next problem arising in these cases involves whether to obtain x-rays of the pregnant victim. Most x-ray departments have signs saying "If you think you are pregnant, tell us and we will not x-ray you." X-ray physicians may panic when they see a pregnant abdomen, and many absolutely refuse to x-ray the woman's hands, head, or anything else for fear that the x-ray will somehow hurt the baby. The smaller the baby, the greater the reluctance to use x-rays. But the damage caused by diagnostic x-rays to a fetus or even an embryo is essentially undetectable. In comparison, the damage that might occur if a skull fracture or a pelvic fracture is missed is absolutely enormous. Therefore, you should x-ray anything that you would have x-rayed had the patient not been pregnant.

Fetal Consequences of Trauma

Let us now return to the plight of the fetus whose mother is involved in an automobile collision. Because the fetus resides in a water-filled, elastic, muscular organ that is entirely surrounded by bone during the first trimester, it is quite unusual for even fairly severe blows to the mother to directly harm the embryo or early fetus. As indicated previously, death of the fetus may be caused by maternal death or shock, but, in early pregnancy, it rarely results from uterine rupture, direct fetal injury, or even placental separation (which, if it occurred at this stage, would simply be called an abortion). This is apparently due to the protection offered by the bony pelvis and the large ratio of amniotic fluid to fetal tissue.

As the fetus grows larger, however, it is more vulnerable to the effects of an automobile collision, as well as other traumatic events. The protuberant abdomen becomes more and more of a target for missiles, knives, or blows delivered in anger. It can also be injured by inanimate objects that the mother may fall against. The further that the pregnant uterus extends out of the protection of the bony pelvis, the more likely the uterus and its contents are to be directly traumatized.

Almost all the reports from our California automobile studies indicated that pregnant trauma victims, even those who were involved in minor collisions and not severely injured, had some complaint of uterine contractions, passage of mucus, passage of bloody mucus, or even outright bleeding. For the most part, this was short-lived.

This observation indicates that trauma did affect the uterus and perhaps caused the release of prostaglandins and other neurohormonal substances that are released in all stressful situations from the medulla of the adrenal gland. As pointed out earlier, rupture of the uterus is quite rare and usually involves the most violent of forces. In most of those cases, rupture of the uterus as incidental to the death of the mother—death that had already been caused by rupture of the lungs, the heart, the liver, and almost all the other internal organs, as well as by head injuries.

Separation of the placenta, however, is a different issue. The further the uterus extends from the protection of the bony pelvis, the more the placenta and the uterus itself are exposed to the direct impact of any forces directed toward the abdomen. This is because the placenta does not contain as much elastic tissue as the uterine wall; therefore, there is a relatively fixed area of the uterine wall over which the placenta is attached. So when a force comes along and compresses the uterus (with the lower part of the uterus being struck, for example, by the steering wheel), it's as if you suddenly struck a large water-filled balloon with a baseball bat. The uterus (or balloon) would flatten against the steering wheel (or baseball bat) and force the amniotic fluid upward, at the same time flattening the uterus in an anterior-posterior diameter. Next, the top part of the uterus would stretch because of the additional fluid in it.

The harmonics of the wave motions set up in the amniotic cavity would continue for a limited period of time, with ever-dampening wave motions stretching the uterus at various rhythms. Basically, these rhythms occur at 90 degrees to one another; the initial flattening of the uterus from front to back would be followed by an enlargement of the uterus from side to side, after which the pattern repeats itself.

On the other hand, although the anchoring villi that hold the placenta to the decidua have some room for give and take, it is less than that of the uterine wall itself. As a result, in about 5% of severe automobile collisions involving women in late pregnancy, the violent harmonic motion of the uterine wall causes separation of the placenta from the decidua. This is, of course, the classic definition of premature separation of the normally implanted placenta. It quite frequently leads to the classic syndrome of cramps, bleeding, uterine contractions, tetany, fetal distress, fetal death, disseminated intravascular coagulation (DIC), and the whole gamut of events that come under the heading of abruptio placentae. Thus, although trauma is not a common cause of premature separation of the normally implanted placenta, that particular problem is overrepresented among pregnant trauma victims.

In the normal course of a pregnancy, it is likely that small areas of placental separation occur. However, the bleeding in these instances is self-limited and, by the end of pregnancy, the small hematoma may be replaced by scar tissue that is indistinguishable from an infarct of the placenta. Some of these minor separations, I am certain, may be caused by traumatic events.

On the other hand, it was fairly clear from the automobile studies that abruptio placentae is generally an all-or-none phenomenon. Although some patients complained of moderate bleeding, bloody mucus discharge, and even contractions, none of those cases seemed to progress to full-blown abruptio placentae.

In those women who appeared in the emergency room following severe collisions and were diagnosed then or later as having abruptio placentae, the diagnosis was obvious from the moment they received professional medical attention. This is a point that takes on particular significance in some legal actions involving pregnant women and unfortunate fetal outcomes. Although it is probably technically possible for a moderate-sized separation of the placenta that occurred earlier and healed itself to result in a small placenta at term, and thus in utero growth retardation or even early death of the baby, this sequence of events is quite unlikely. Science and our best evidence at present indicate that if bleeding, cramping, and passage of bloody mucus cease within a few days of the traumatic event, with the fetus never having indicated any evidence of fetal distress, something that occurs weeks later would not necessarily be a result of the trauma—despite what the lawyers might claim.

In most situations, even with fairly severe blows to the pregnant abdomen, the elasticity of the uterus and the incompressibility of the amniotic fluid combine to protect the fetus far beyond what seems possible. There have been reports of women, near term, who have fallen from the third floor of buildings and landed directly on their abdomen without suffering any injury to the uterus, the placenta, or the fetus.

The Trauma of Violence

Although much of my experience in treating trauma in pregnant patients involves automobile accidents, there are a variety of interesting comments in the literature regarding trauma to the fetus from other sources.[1,2] In late pregnancy, the pregnant abdomen, as stated earlier, makes a very large target for hostility. Gunshot wounds, ice pick maneuvers, and the use of fists and feet of an assailant have all been frequently reported as causes of fetal injury. Those injuries range all the way from complete crushing of the fetal skull to fractures of virtually every bone. In one case, initial x-rays indicated that a bullet had entered the fetal heart. However, when the baby was delivered by cesarean section and an autopsy done, the bullet was retrieved from the popliteal artery to which it had apparently traveled while the fetus was dying. In this instance, the cesarean section was probably performed unnecessarily. In another shooting incident involving a near-term fetus, x-rays located the bullet within the body of the fetus. The bullet was removed during a cesarean section, and both the mother and baby survived.

Although this kind of fetal therapy can produce successful results, the opportunity for it is quite rare. In most cases, the fetus is too small to be able to survive both the premature delivery by cesarean section and the surgical procedure and anesthesia on the fetus itself required to repair the damage. Furthermore, the knife wound or bullet may not actually be in the vital part of the fetus and a cesarean section would thus be unnecessary for fetal survival.

That is not to say that all modalities should not be brought to bear to locate the path of the penetrating object, to find the bullet if a gunshot wound is involved, and to attemt to ascertain its effect on the fetus. Fetal monitoring may be of great help in this, along with the use of both x-rays and ultrasound scanning. All these should be employed as often as necessary to determine whether or not exploratory surgery should be performed.

Assessing the Fetus

Treatment of the pregnant trauma victim should include a thorough assessment of fetal viability and salvageability. Basically, if the pregnancy is advanced less than 26 to 28 weeks, there is little likelihood of being able to alter the course of whatever might have happened to the fetus. If that course simply involves uterine contractions, with or without early changes in the cervix, the stability of the mother might permit routine tocolysis. It should be pointed out, however, that if the fetus itself is undergoing any bleeding, the administration of B-adrenergic drugs is counterproductive and actually increases the likelihood of fetal shock and death.

Furthermore, it is very difficult to detect the presence of fetal bleeding. An enormous amount of blood must appear in the fetal abdomen for it to become obvious, even with the use of ultrasound. Although less blood needs to appear in the fetal brain for it to be medically detectable, it is a more difficult diagnosis to make in a fetus than in a newborn.

Feto-maternal bleeding may occur as the result of trauma. It is suggested that, in hospitalized trauma victims near term (where a cesarean section could salvage the infant), Kleihauer-Betke examinations be performed to detect feto-maternal bleeding. If the Kleihauer-Betke tests show no evidence of feto-maternal bleeding, none is likely to occur later. If the results of the tests are positive, you can calculate the amount of feto-maternal bleeding and act appropriately.

I have been impressed in the last few years by anecdotal reports by various interested physicians. There does appear to be an unusual type of chronically developing abruptio placentae that occurs more frequently in automobile trauma victims than in association with the usual nontraumatic premature separation of the normally implanted placenta. In fewer than ten cases, one of which was published recently in *Obstetrics and Gynecology,* the pregnant woman experienced some bleeding, cramping, and passage of mucus following an automobile accident and then a diminution of these symptoms.[3] But over a course of several days, the bleeding started again and continued for up to ten days prior to a greater separation of the placenta and ultimate death of the fetus.

In my experience with the more typical obstetrically related abruptio placentae, this is a decidedly unusual set of circumstances, and I have no ready explanation for it. Perhaps it is something specifically related to trauma, but I do not understand the mechanism at all. Also, I know of no simple way of studying this issue at the moment because of the ever-increasing difficulties in studying pregnant trauma victims.

This type of phenomenon demonstrates the need, in trauma cases, for the fetus to be observed for a longer period of time than the mother, if only from the standpoint of medicolegal considerations. Although the mother may be found to have no serious injury, and 30 or 45 minutes of fetal monitor strip may reveal a normal tracing, there appear to be enough cases of chronically developing abruptio placentae and feto-maternal bleeding to justify admitting maternal trauma cases to the hospital long enough to take two successive Kleihauer-Betke tests; this means that the woman would be under observation for a minimum of 12 to 24 hours, with the fetal heart rate being traced for that length of time. This approach increases the likelihood of detecting a fragile fetus and is certainly more prudent than simply declaring that the fetal heart is normal, the mother is not seriously injured, and ordering a quick discharge of the patient. A certain number of intrauterine fetal deaths do occur within a few days of an occurrence of trauma; at least some of these may be prevented if the mother is kept in the hospital for a sufficient period of time and observed particularly for fetal distress and feto-maternal bleeding.

This advice, of course, applies only to a fetus who would be viable should a cesarean section be deemed necessary. There is little point in detecting feto-maternal bleeding or chronically developing abruptio placentae if the baby has been in the uterus less than 24 to 26 weeks.

Further treatment options include vasoconstrictors, which, in my opinion, should not be used in pregnant victims because of the extreme sensitivity of the uterine arteries to these drugs and because hypovolemic shock rarely responds to vasoconstrictive therapy. Uterine blood flow may be so compromised by the combination of drug-induced vasospasm in the uterine artery and hypotension due to blood loss that the fetus may die unnecessarily. Ephedrine, which usually avoids uterine artery spasm if neurogenic shock is present, is a worthwhile agent in cases where there has not been extreme blood loss, or where the blood has been replaced.

Abdominal injuries are usually multiple in trauma cases and often involve the pregnant uterus and its contents or its adnexa. Parametrial hemorrhage is common among seriously injured pregnant women. Pelvic fractures increase the probability and the risk of bleeding in and around the pregnant uterus. (When the ring of the pelvic bones is broken, there is a great likelihood that the fetal head, in a term pregnancy, will be fractured at the same time.)

The bowel may also be injured in seriously hurt pregnant accident victims, but, because it hides behind the pregnant uterus, it is not involved as frequently as when a victim is not pregnant. On the other hand, rupture of the spleen is thought to be more common among pregnant victims, a point of information that the obstetrician should keep in mind.

Detecting Intraperitoneal Bleeding

Although it has been frequently noted that there are *two* patients' interests to be considered when the accident victim is pregnant, the interests of the fetus generally coincide with those of the mother. The presence of the fetus should not delay or compromise maternal therapy. If anything, it increases the need for prompt action. For example, pregnancy imposes an even greater urgency to correct hypotension quickly. If intraperitoneal bleeding is suspected, the earlier the laparotomy and control of the bleeding, the better for both the mother and the fetus.

Trauma surgeons have for years used various techniques to look for intraperitoneal bleeding before it progresses to the point where the patient goes into shock and thus becomes high-risk for exploratory surgery. Probably the most effective of these is the technique of peritoneal lavage reported by Thal and Shires.[4] The presence of the protuberant pregnant abdomen should not be a serious deterrent to the use of peritoneal lavage, provided that an ultrasound machine is available to identify which areas of the protuberant abdomen are uterus and which are not uterus, so the peritoneal lavage catheter can be placed away from the uterus. The following findings indicate the possible presence of intraperitoneal bleeding and the need for exploratory laparotomy:

- The direct aspiration of more than 10 mL of blood
- Grossly bloody lavage fluid
- Lavage fluid returned through the Foley catheter in the bladder or through a chest tube
- A red blood cell count in the lavage fluid of greater than 100,000/mm^3
- A white cell count of greater than 500/mm^3
- An amylase concentration of greater than 175 Somogyi units per deciliter (which indicates that the pancreas has been injured and that surgery is necessary)

The researchers also suggested that if any of these findings was equivocal, the test should be repeated at a later time. They considered the test to be negative if the results were as follows: a red blood cell count of less than 50,000/mm,^{3} a white cell count of less than 100/mm,^{3} or an amylase of less than 75 Somogyi units per deciliter.

Another site to check for injury in the pregnant victim of blunt abdominal trauma is the urinary tract. This may be a particular problem area during middle-to-late pregnancy because of the prominence of the bladder being forced out of the pelvis by the pregnant uterus, the descent of the fetal head, and the increased amount of urine generated during the pregnant state.

Thus, a urine specimen should be obtained from any pregnant patient with a significant degree of trauma. In cases where the victim is comatose or cannot give a specimen, a catheter should be passed into the bladder. If the urine is perfectly clear, there is no need to look further. However, bloody urine or obstruction of the passage of the catheter should prompt immediate urologic consultation to ascertain the integrity of the urinary tract.

Up to this point in treatment of the mother, it is clear that whatever tests and immediate management are necessary for the mother are also likely to work in the best interests of the fetus. However, the interests of the fetus may conflict with those of the mother during laparotomy. Colon rupture or bleeding in the retroperitoneal space may require the emptying of the uterus for proper exposure and repair of these life-threatening injuries. Thus, cesarean section with sacrifice of a young fetus may become necessary to save the life of the mother. In most cases, however, maternal injuries may be repaired without disturbing the pregnancy. Even when the fetus is known to be dead prior to abdominal surgery, hysterotomy usually serves no clear-cut beneficial purpose, and will require the mother to have a cesarean section if she plans to have additional pregnancies. It has been reported by several authors that labor and vaginal delivery even a few hours after laparotomy are well tolerated provided enough analgesics are available.

Although the principles of treatment outlined in this presentation are appropriate for a general discussion and understanding of trauma management in pregnant victims, for more detailed descriptions of minute-to-minute treatment see references 1 and 2.

Medicolegal Considerations

One of the most difficult situations faced by a physician is to be asked by a patient's lawyer whether a traumatic event—an automobile collision, a fall, a beating—"caused" something to happen to the pregnancy—abortion, fetal death, premature labor, or premature separation of the placenta. There is little experience upon which to base an opinion. The problem is that pregnancy in itself is a precarious state: Abortion or premature labor may occur, the fetus may die, the placenta may separate, all without any known "cause." The vast majority of such complications ocur in the absence of trauma of any kind. In addition, even traumatic events that seriously injure the mother are only infrequently followed by pregnancy loss. With these inconsistencies in mind, the physician's stated opinion will often coincide with the claims made by his or her patient. This may serve the patient's interests—but may not serve justice.

The law has difficulty dealing with the status of the fetus, as demonstrated by the wording of the Supreme Court's 1973 decision on abortion. In that instance, the Supreme Court clearly felt that since the fetus, at least through the first trimester, is not capable of life apart from the mother and is therefore not viable, it is up to the mother to decide whether to continue or terminate the pregnancy. During the second trimester, some fetuses are capable of living apart from the mother, and by the 28th to 30th week, more than half of fetuses survive following delivery. It is generally considered that a fetus that is 26 weeks, or weighs more than 750 g, is viable; many 24-week fetuses have survived.

The distinction between viable and not viable changes with medical advances, but the distinction is crucial in the law: No state allows recovery for damages on the part of the fetus if it is not legally viable. In Oklahoma, for instance, the fetus is considered a part of the mother until birth and, as such, does not actually exist from a legal standpoint. However, damages may be recovered by the mother for her own injuries related to a collision and, if the fetus is lost because of these injuries, that would likely increase the amount of the award. Because of this, the physician must be as accurate as possible in discussing with his or her patient any link between the collision and fetal loss or injury.

This part of the presentation will outline criteria that can be used to establish a probable cause-and-effect relationship between a collision and a subsequent fetal loss. If these simple criteria are met, a causal relationship probably exists. If they are not met, then the relationship is either questionable or nonexistent.

First, the pregnancy should have been progressing normally up to the time the accidental trauma occurred. Patients who experienced bleeding and uterine cramps a few days prior to a minor collision were probably in the abortion process at the time of the collision. Even though the abortion followed the collision, it may not have been caused by it.

Second, there should be a close temporal relationship between the traumatic episode and the process leading to fetal loss. For instance, a woman who reports premature rupture of the membranes starting within minutes of an automobile collision probably did suffer a traumatic rupture of the membranes. However, if the membranes did not rupture for several days or weeks following the collision, the rupture most likely was unrelated to the accident. Time is of the utmost importance in making such determinations.

Third, the fetus and placenta should be carefully studied after delivery to be certain that their appearance is compatible with an injury that could have been caused by the trauma. A study of aborted material passed two days following an automobile collision might, for example, reveal that it was a typical blighted ovum. In that case, the collision can hardly be blamed for the abortion, which was inevitable from the outset. Similarly, the x-ray appearance of a fracture of the clavicle in a live newborn may easily establish whether the bone was broken during a collision three weeks prior to delivery or during the delivery itself.

Fourth, there should be an absence of risk factors known to cause the type of pregnancy complication alleged to have been caused by the automobile collision. For instance, consider the case of a woman who has had three previous normal pregnancies: She has a more substantial claim for damages for premature delivery two days following an automobile collision than a woman who has had three previous premature labors. Similarly, a traumatic etiology for abruptio placentae is easier to support in a normotensive woman than in one with severe chronic hypertension (a condition that increases the risk of premature separation of the placenta).

As noted in our California Highway Patrol studies, trauma is rarely followed by interruption of pregnancy, unless there has been serious or life-threatening injury to the mother. Even in cases of severe maternal injury, the pregnancy is not always involved. It is difficult to legally establish a causative relationship between a traumatic event and damage to the pregnancy, and this is as it should be. In the first place, traumatic events are not often followed by fetal injury or death. When, in early pregnancy, traumatic events are followed by abortion, the pregnancy usually proves to have been defective. The author agrees with Hertig and Shelton and with the court of Louisiana on the following points: Evidence to prove the causative relationship between the trauma and the injury should be subjected to the strictest examination; and the burden of proof should rest with the person who alleges that such a relationship exists.

If the four criteria suggested in this presentation are met, it is unlikely that trauma-induced pregnancy injury would go unrecognized. Nor is it likely that a pregnancy injury unrelated to the trauma would be compensated. It is possible, of course, that an occasional pregnancy injury that was caused by a traumatic event, but that did not meet the criteria, would go uncompensated. However, this would be such a rare occurrence that it would result in less overall injustice than if the reverse were the case. For more detailed discussion of the medicolegal aspects of traumatic injuries during pregnancy, see references 5 and 6.

Discussion of this article by the following panelists: Drs. Warren Crosby, Samuel Pasquale, Gilles R.G. Monif, Roy H. Petrie, and Jack Pritchard is available from Ortho Pharmaceutical Corporation, Raritan, New Jersey 08869.

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Planning a CSMS Statewide IPA-HMO

WILLIAM A. WHALEN, M.D.

We physicians have faced many challenges over the years influencing our practices and commitment to provide the highest quality medical care to our patients. It is imperative that we, through CSMS, continue to establish creative solutions against those forces that would fragment our strength and inhibit our ability to provide quality health care.

It is within this context that the CSMS House of Delegates directed the Council to establish an ad hoc committee to study the desirability of developing a statewide physician-owned, for-profit, IPA-type Health Maintenance Organization (HMO). It appears that the project is indeed feasible for Connecticut and puts us in the forefront of a trend that is being established nationally. Four other states, Georgia, New Hampshire, Mississippi and South Dakota, are now developing statewide IPA-HMOs that are *wholly* capitalized and controlled by physicians.

The CSMS ad hoc IPA-HMO committee has isolated at least seven advantages to practicing physicians for establishing this program:

1. Provide a third party payor (HMO) in which medical decisions would be made by medical doctors.
2. Provide a single health service delivery system for all areas within the state. None of the nine HMOs, nor any IPA in Connecticut is statewide.
3. Re-establish the physician-patient rapport which is rapidly eroding as alternative delivery systems redirect patient care in ways that suit the corporation rather than the patient.
4. Maintain policy control in the hands of physicians, perhaps through a mechanism similar to that of our highly successful CSMS professional liability insurance company, CMIC.
5. Reduce the ability of commercial insurance carriers and national HMO firms to further fragment health care delivery and physician influence in the state.
6. Establish a cost-effective administrative system (HMO) that will keep more dollars available for health care, and allow physicians to control the administrative costs for health care rather than having administrative fees arbitrarily set by insurers.
7. Establish a program so that the profits which are attracting commercial companies to this business are distributed instead for the benefit of participating physicians and their patients.

CSMS is prepared to continue the development process of a statewide IPA-HMO, but it is imperative that our physician membership strongly support this program. The insurance department has indicated that they will require at least 50% statewide physician participation before granting a license.

Additionally, in order to own and operate a physician plan (IPA-HMO), *we* will have to capitalize it. Preliminary financial estimates indicate that between six to ten million dollars will be needed and must be raised through a stock offering to participating physicians. While this may sound formidable, it is, in fact, a small investment for 3000 physicians who are determined to preserve their leadership and control in patient care over the future years of their practice.

Physicians are beginning to realize that in order to control their patient base within a prepaid program, control over the HMO is imperative. Controlling an IPA that contracts with HMO's does *not* accomplish this. As a practical matter, for physicians to be able to ensure the provision of quality care in an HMO environment requires them to control the HMO license and hence, the flow of premium dollars into the organization.

The feasibility report and a detailed business plan will be ready for presentation to the CSMS House of Delegates in May. Once again, as in 1984, physician solidarity will be *essential* to direct our own professional destiny.

WILLIAM A. WHALEN, M.D., President of the Connecticut State Medical Society, and a practicing surgeon in Willimantic, CT.

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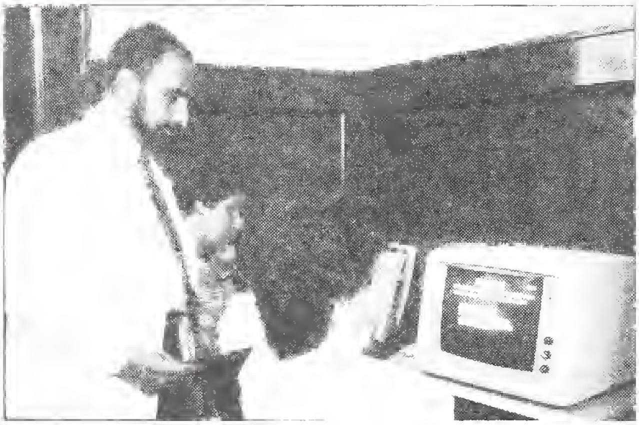

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Closing the Gaps in Health Insurance Coverage

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A certain segment of the US population can be characterized as "falling between the cracks" in regard to having adequate protection against health care expense. These are persons whose age or economic status precludes their eligibility for protection under tax-supported programs such as Medicare or Medicaid but who find it financially very difficult to purchase adequate health insurance coverage—or any coverage—in the private sector.

Using data drawn from the 1977 National Medical Care Expenditure Survey, which were adjusted to account for improvements in the catastrophic protection offered by group major medical insurance from 1977 to 1984, Farley[1] recently estimated that anywhere from 24% to 37% of the US population younger than 65 years lacks adequate health care coverage, with an intermediate estimate of 26.7%, or 50.7 million people. This segment of the population includes persons whom Farley estimates are uninsured all year (9%), uninsured part of the year (9.4%), and the underinsured (5.1% to 18.3% of the under 65 population with private insurance). Farley based her estimates of the extent of underinsurance on various probabilities that individuals with private insurance will incur large medical expenses. To derive her intermediate estimate (8.3%), for example, Farley assumed that an individual is underinsured if he or she has at least a 1% chance of incurring out-of-pocket expenses for hospital and medical care that amount to 10% or more of his or her annual income.

On the demand side of this issue, Farley found that the population lacking adequate health insurance protection is heterogeneous but that females, part-time employees, the self-employed, the unemployed, persons in poor and fair health, and the poor and persons of low income have the highest levels of no insurance and underinsurance. On the supply side, Farley's study indicated that underinsurance is a substantially greater problem in nongroup health insurance programs. Twenty-two percent of all persons with private insurance have individual policies, and, again, the low income, unemployed, part-time employed, and self-employed tend to be more likely to have individual insurance plans.[2]

The segment of the population lacking adequate health insurance protection can be divided into the following subgroups:

- The short-term unemployed and their dependents who have lost their employment-based insurance coverage.
- Persons uninsurable for medical reasons (ie, poor health, previous medical history, or employment in a medically hazardous occupation).
- The "premium indigent"—persons who are standard risks medically, and who may or may not be in the labor force, but who do not have access to group coverage or do not have adequate group coverage and cannot afford the premium for adequate individual coverage at standard rates.

In 1983, there were an estimated 6 million temporarily unemployed persons and their dependents in the US who had lost their employment-based health insurance coverage[3] and approximately 1 million persons who were considered medically uninsurable.[4] The remaining 43.7 million of the estimated 50.7 million persons

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lacking adequate health insurance protection can be identified as the "premium indigent."

After careful consideration of the issues involved and various alternative approaches, the American Medical Association (AMA) Council on Medical Service, Council on Legislation, and Board of Trustees proposed the establishment of state private insurance pools for addressing the needs of the short-term unemployed and state risk-pooling programs for addressing those of the medically uninsurable. Both of these proposals are presented in this article. Although these proposals only address the needs of the two smallest subgroups of the entire uninsured and underinsured population, it is felt that each of these subgroups is of sufficient dimension to merit solutions to their unique problems.

The concluding section of this article discusses various approaches currently under study by the Council on Medical Service to meet the needs of the third and the largest subgroup—the premium indigent. The article identifies important policy issues and questions that will need to be addressed in developing solutions to the needs of this heterogeneous group.

The Short-term Unemployed

The issue of health care and health insurance coverage for the unemployed is not new. The United States has not achieved full employment for decades, and there has been a substantial level of unemployment among Americans over this time. At the beginning of the current decade, however, the economic recession produced even higher levels of unemployment in the nation as a whole, while specific areas of the country experienced unemployment nearly double the national rate. While many states require employers to continue health care benefits for their employees following unemployment, the average required duration of such continuation is three months, and many of the unemployed eligible for such continued benefits remain unemployed after their eligibility period has ended. It was estimated that some 6 million individuals and their dependents lost their employment-based health insurance coverage in 1983 due to unemployment.[3]

The newly unemployed person is usually precluded from participation in Medicaid or state and local general assistance programs since, when income from active employment ends, these individuals usually have significant assets, such as homes, cars, and furnishings, and public programs are generally limited to those who are without such assets or other financial means. To compound this situation, because of their loss of income and because of the higher cost of individual health insurance policies compared with group benefit plans, many of the unemployed are financially unable to obtain adequate health insurance coverage for themselves and their families.

In response to this problem, the AMA's Council on Legislation developed a proposal for a temporary national program to provide health insurance for the unemployed, which was concurred in by the Council on Medical Service and approved by the Board of Trustees and House of Delegates. The proposal calls for a program based on the following principles:

- It should have limited eligibility and be targeted among the unemployed.
- While government must have a role, the program should be administered in the private sector and provide private insurance coverage. Financing should be a shared responsibility of government and the private sector.
- It should avoid disruption in continuity of care for the individual and his or her family and, to the extent possible, in continuity of health insurance coverage.
- It should provide benefits limited in scope and provide for freedom of choice of providers.
- It should be aimed at a short-term solution for the temporarily unemployed and not create a new entitlement program.
- It should be subject to early and ongoing Congressional and public review and evaluation.

Under the proposal, unemployed individuals would be covered by a private insurance pool in each state that would write individual policies. If necessary, each state would enact legislation authorizing such an insurance pool. Participation in the pool would be required of all entities in the state that provide or make payment for medical care under a group health benefit plan, including self-insured groups and health maintenance organizations. It should be noted, however, that to ensure the inclusion of the self-insured groups in this pool, either a change in the law established under the Employment and Retirement Income Security Act (ERISA), which prohibits state regulation of self-insured groups, or the development of tax incentives encouraging the participation of self-insured groups would be required.

If a private pool is not established voluntarily within six months after legislation is enacted, the state insurance commissioner would be responsible for requiring that the pool be established, approving the premium rates and reviewing information issued by the pool. To provide for a rapid start-up while the insurance pool is being formed, the program should be administered by an existing state agency (eg, Medicaid), provided that the actual coverage is furnished through the private sector from the outset.

To finance pool coverage, unemployed individuals would pay a portion of the premium using a sliding scale based on total family income (both earned and unearned) and an affordable level of deductibles and coinsurance for all covered services. State, and in some cases, federal payments would also be made to support the pool. Federal funding would be dependent upon minimum national and state unemployment rates and, if required, would be based on a sliding scale related to the state's level of unemployment weighted by the covered population. If the pool's yearly expenses exceed federal and state payments and the premium payments of covered persons, each entity participating in the pool would be assessed for the shortfall based on their underwriting activity in the state for that year.

An unemployed person would be eligible for coverage under the pool for a period equal to the time in which they have a right to receive regular, extended, or federal supplemental unemployment compensation. Persons who are eligible for health insurance coverage under their former employer's group health plan or under Medicaid, Medicare, or any other government health program and persons who are eligible to obtain coverage as a family member of a person eligible for employment-based coverage would not be eligible for this program.

The program should cover medically necessary services and provide for free choice of provider. Benefits would be set at the state level, but if a state accepts federal funding, the following minimal benefits would be required:

- Specified inpatient services (eg, 14 days per year).
- Emergency services.
- Physicians' services, including outpatient services provided in a physician's office or clinic; inpatient services; prenatal, maternity, and postpartum care; and diagnostic laboratory and radiology services.

The program should automatically terminate at the end of two years unless specific action is taken to extend it. During these two years, as an incentive toward participation in the pool by all insuring entities, an employer would be required to purchase group health coverage from an entity participating in the pool in order to be allowed to deduct the cost of group health insurance premiums for its employees. Self-insured groups would also be required to participate in the pool in order to deduct the costs of their health benefit plans. In addition, these deductions would only be allowed if the employer provides for a period of open enrollment of at least 30 days immediately after an employee, who is eligible to enroll in the plan, loses his or her coverage under a spouse's or other family member's plan due to the unemployment of the spouse or family member.

Following House of Delegates' approval of this proposal, the AMA developed draft federal legislation for introduction into Congress to establish such a program.

The Medically Uninsurable

Most estimates indicate that approximately 1 million persons are unable to obtain health insurance coverage in the private market because of poor health status, previous medical history, or employment in a medically hazardous occupation. While this number is proportionately small, it is far from insignificant.

At least seven states (Connecticut, Florida, Indiana, Minnesota, North Dakota, Rhode Island, and Wisconsin) have legislation creating or authorizing a risk-sharing pool or reinsurance association to offer health insurance at reasonable cost to persons who are high risk or "uninsurable" under conventional underwriting standards. Generally, these programs are targeted toward enabling the purchase of health insurance coverage by individuals who, because of poor health status or previous medical history, would otherwise be unable to obtain such coverage or only purchase it at excessively high rates.

Interestingly, information from two of these states whose pooling programs have been in operation for a relatively longer period—Connecticut (1975) and Minnesota (1976)—indicates significant growth in the number of individuals who use this mechanism to obtain coverage. In Connecticut, the number of individuals enrolled in the state's pooling arrangements increased from 7,160 in December 1979 to 9,803 one year later—a 30% increase. Similarly, the number of policies in effect under Minnesota's program increased from 1,608 in December 1979 to 2,656 in August 1981—a 57% increase.

Based on the rate of growth in these and other state programs, the Council on Medical Service agreed in 1983 that the need for such coverage was sufficient to merit development of similar programs in all states. Accordingly, the Council developed the following recommendations concerning such programs, which were approved by the Board of Trustees and House of Delegates.

1. Each state should enact legislation establishing special risk-pooling programs to ensure that adequate health insurance coverage is available at a reasonable cost for those who would otherwise be unable to obtain such coverage because of medical considerations.

Legislation establishing a state risk-pooling program should allow individual carriers the option of issuing comparable coverage directly, reinsuring through the pool, or forming more than one pool if desired. This flexibility will allow recognition of different underwriting practices and philosophies among carriers, avoid inequitable assessment of any one type of carrier, and enhance "consumer choice" in this population group.

2. All health care financing entities in the state, including commercial insurers, nonprofit medical service plans, health maintenance organizations, and self-insured groups, should be required to participate in the program either through pool membership or the offering of comparable coverage individually.

Only with such uniform participation can adverse selection be avoided and a financial base sufficient to support the program be ensured. It should be noted, again, that either a change in the law established under ERISA, which prohibits state regulation of self-insured groups, or the development of federal tax incentives encouraging the participation of self-insured groups will be required to ensure the inclusion of this group in such a state program. Since these recommendations were adopted, the Council on Legislation has prepared and the Board of Trustees has approved for introduction into Congress a proposed amendment to effect the necessary change in ERISA.

3. There should be minimum and maximum limits on the premiums for coverage offered by these state programs. The minimum premium level should be set above the average standard rate for individual coverage to ensure that the program is used only by those for whom it was designed—the medically uninsurable.

Specific recommendations for these lower and upper limits are more difficult to make given the relative newness and lack of utilization data for most of the current programs now operating. For now, the Council suggests rates of at least 125% but not more than 150% of standard individual rates. More experience with existing and additional state programs, using different premium limits, will indicate whether any modification is needed to ensure that premiums will not be so low as to result in unacceptable costs to carriers and needless competition with the regular insurance market on the one hand, nor so high as to seriously limit affordability of the coverage on the other.

4. To supplement the "screening" function afforded by the higher premium levels, specific criteria of eligibility for pool coverage could also be used to ensure that the coverage is used only by those for whom it is intended.

Such criteria could also include minimal waiting periods or preexisting condition standards, simply to deter individuals from going without any coverage until they become sick and then applying for pool coverage.

5. Coverage offered under state programs for the medically uninsurable should meet required standards as to type of benefits and as to limits on the amount of cost sharing by beneficiaries.

Ideally, requirements in appropriate enabling legislation would be specific as to types of benefits and amounts of cost sharing required, with the general provision that such benefits be similar to those available to most state residents through the regular insurance market. At minimum, such benefits should be identified as "comparable to those typically provided through large employer groups."

The Premium Indigent

The remainder of the uninsured population includes a certain portion of self-employed and part-time employed, employees in firms without health insurance, and families with no active member in the labor force. Together with those classified as underinsured, these persons constitute the majority of those with inadequate or no protection against health care expenses.

Because the "premium indigent" are a heterogeneous group, it is likely that approaches to improving health expense coverage for this population segment will need to be similarly multifaceted. One obvious approach to ensuring adequate health care coverage for this group would be to expand and liberalize the criteria of eligibility under tax-supported assistance programs such as Medicaid, including liberalized "spend-down" provisions for individuals at marginal income levels. Currently, several states are considering extending Medicaid coverage to the premium indigent. However, if government places a cap on Medicaid expenditures, it is unlikely that these plans will be implemented. Given the current political and economic climate, including the federal deficit, the Council on Medical Service questions in its study of this group whether extending Medicaid coverage is a realistic approach at this time. The Council also believes that, as a general principle, it is desirable to retain coverage for this group in the private sector to the degree possible.

A number of possible approaches to dealing with this problem in the private sector are currently under consideration by the Council. These include the following:

- Mandating that all group and individual health insurance plans provide a dollar limit on the insured parties' out-of-pocket liability, or that all insurance companies and plans make available coverage providing such a dollar limit.

Among the questions requiring study in this approach are the affordability of such expanded coverage—particularly for the premium indigent group—and whether plans should be required to simply make such coverage available, provide it in all offerings, or be encouraged through tax incentives to make such coverage available.

- Requiring individuals who are able to do so to purchase such catastrophic coverage.

This approach raises basic questions regarding individual rights and restraint of choice, as well as inefficient use of premium dollars to purchase unneeded coverage in some instances.

- Requiring that private health insurance be made available by employers to all employees (including part-time employees) and their families.

Restraint of choice is one of the important issues in this approach as well, for both employers and employees, as are the potential costs of such an expansion, the source of payment for such costs, and the impact on unemployment.

- Privately sponsored or publicly mandated "pooling" insurance arrangements among the self-employed and those not in the labor force.

Establishment of statewide risk pools may provide at least an interim answer to making "group" coverage more accessible to the self-employed and / or part-time employed, as well as those not in the labor force. However, adverse selection may become a problem if only the "high-users" of health care opt for pool participation. In addition, even risk pool offerings may not be affordable to those at marginal income levels without special subsidies. Furthermore, methods for ensuring participation in such pools by self-funded plans must be found. As noted previously, ERISA precludes nearly all state regulation of self-funded health benefit plans; any state legislation that could not require participation in risk pooling by such self-insured plans along with other plans might encourage even more employers to self-insure and thus defeat the idea of risk-pooling. Appropriate federal tax incentive legislation may be the most effective answer to participation in state pooling arrangements.

These and other policy options will be studied further by the Council as the basis for developing proposals to improve the accessibility and affordability of adequate health insurance protection for this sizable segment of the population. It is likely that society as a whole already bears the cost attributable to the lack of adequate health care coverage for this group, whether through lost man-hours and productivity or through defraying the economic burden of uncompensated care. The question, therefore, is not whether such costs should be met, but *how* they can be met in a way that best maintains and preserves the health of this population group while apportioning this cost equitably over all sectors of the health care economy.

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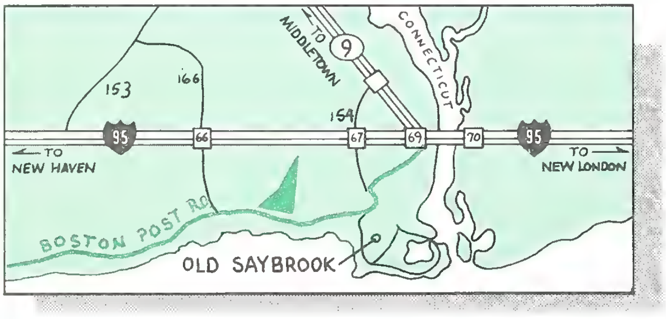

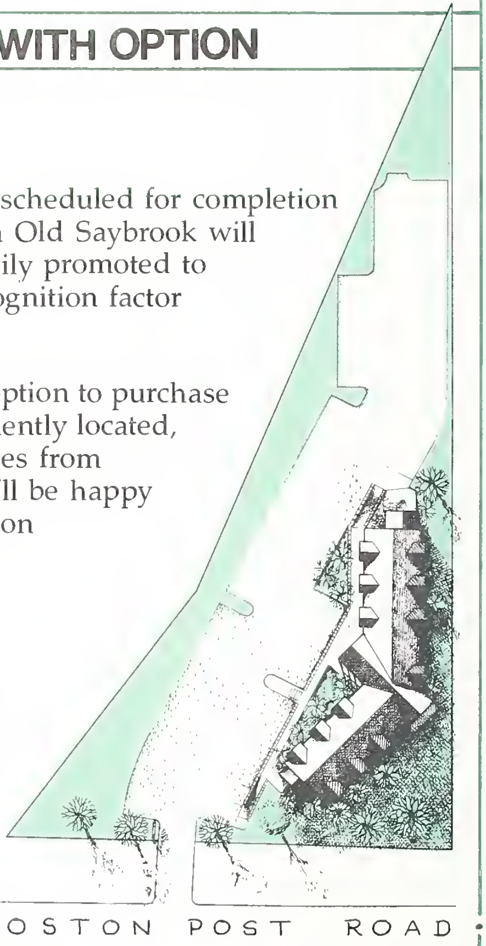

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Drug-Induced Ototoxicity

BERIT GUNDERSEN, PHARM.D.

Introduction

Many different classes of drugs can cause ototoxicity, which may be vestibular or cochlear. The cochlear effects range from production of temporary tinnitus to permanent deafness, while the vestibular effects range from lightheadness and giddiness to vertigo. The most frequently used drugs that cause ototoxicity include the aminoglycosides, salicylates, loop diuretics, and antimalarials.

Aminoglycosides

The aminoglycosides are commonly associated with ototoxicity, probably from destruction of sensory hairs in the inner ear. The hairs involved are more sensitive to cochlear changes although vestibular changes can also occur. High frequency sounds are processed in the basal end of the cochlear, and it is these cells that are initially affected. As the lesion advances it progressively involves the hair cells toward the apex which leads to deficiencies in lower frequency hearing.[1,2] It is important to remember that the inner ear of the fetus may be susceptible to these toxicities.[1]

The potential for these drugs to cause ototoxicity can be explained by their tendency to accumulate and remain in the perilymph for long periods of time.[3,4] The signs and symptoms of ototoxicity caused by the aminoglycosides do not always occur during the course of therapy but may appear days to weeks after completion of therapy. The ototoxicity is related to the serum levels, total dose and is increased in the presence of renal failure. Aminoglycosides are potential ototoxins when used parenterally, orally, for wound irrigation, intrapleural instillation, or applied to broken or burned skin. The use of ear drops containing aminoglycosides has been shown to be ototoxic in animal studies but *not* in humans as long as there is no perforation in the tympanic membrane.[2,3]

In the severely ill patient it may be difficult to differentiate vestibular damage from the disease state as it can present as lightheadness, anorexia, vomiting, or vertigo. In most cases this effect is compensated centrally and all signs and symptoms will abate.[3] The cochlear damage is more often permanent.[1-5]

See Table 1 for comparative ototoxic potential of aminoglycosides.[6]

Table 1
OTOTOXIC POTENTIAL OF AMINOGLYCOSIDES

Drug	*Cochlear*	*Vestibular*
Amikacin	++	+
Gentamicin	+	++
Kanamycin	++	+
Neomycin	++++	+
Netilmicin	+	++
Sisomicin	+	++
Streptomycin	+	+++
Tobramycin	+	+/++

To avoid or minimize ototoxicity associated with aminoglycoside therapy the following is recommended:

1) Maintain aminoglycoside serum levels in the normal range (i.e. gentamicin and tobramycin peaks less than 10 mcg/ml and trough levels less than 2 mcg/ml).[2]
2) Monitor renal function and adjust dose accordingly.
3) When administered locally, the total daily dose should not exceed the amount that would be administered by intravenous or intramuscular injection.[1]
4) Oral neomycin should not be administered in doses in which the amount absorbed exceeds the normal I.V. guidelines. Approximately 3% of oral neomycin is absorbed systemically.[1]
5) In presence of perforation in tympanic membrane, antibiotic ear drops should not be prescribed.
6) Avoid intravenous neomycin as it has been shown to cause progressive and irreversible damage even if drug is discontinued.[2]
7) Avoid concomitant use of loop diuretics (especially ethacrynic acid) and aminoglycosides since both classes of drugs have known ototoxic potential.[7-11]
8) Monitor audiograms in selected high risk patient groups (i.e. pre-existing hearing loss). Cochlear toxicity occurs 8-10 days into therapy. The baseline audiograms may be obtained during the first 72 hours of therapy.[3]

Other Antibiotics

Erythromycin when administered parenterally in large doses (4 gms or more per day) has been shown to cause temporary hearing loss and/or tinnitus.[1] Since

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few patients receive such high doses, ototoxicity is not a major problem with this drug.

Vancomycin can cause a permanent senorineural deafness that can be associated with tinnitus. The incidence of this toxicity is very low and is generally associated in patients with renal failure, serum levels greater than 90 mcg/ml,[1,2] and the concomitant use of aminoglycosides.

Capreomycin and viomycin are potential ototoxic antibiotics reserved for the treatment of drug-resistant tuberculosis. Viomycin appears to be more toxic than capreomycin.[12] To avoid ototoxicity with viomycin the adult dose should be administered in 1-2g daily doses for short periods of two or three weeks. Thereafter the dose is reduced to 2g twice weekly.[12] The ototoxic effects of capreomycin can be avoided or reduced significantly if the drug is not administered to patients with pre-existing hearing loss or to patients with renal function impairment.[13]

Loop Diuretics

The hearing changes caused by these drugs are usually temporary although permanent cochlear damage may occur. The postulated mechanism for this ototoxicity is changes in the ionic composition of the endolymph which can lead to cell dysfunction or death.[5] Ethacrynic acid is more ototoxic than furosemide.[8] Animal studies have shown ethacrynic acid to be ototoxic in single doses of 30-50 mg/kg or 10 mg/kg if the dose is repeated within two hours.[2] To avoid potential permanent ototoxicity avoid giving high doses, repeated doses in rapid succession, and when possible avoid concomitant use of other ototoxic drugs.

Salicylates

The salicylate doses associated with hearing changes, primarily tinnitus, are those commonly used for treatment of diseases like rheumatoid arthritis (anti-inflammatory doses). Isolated cases of permanent hearing loss have been reported in patients surviving salicylate poisoning.[5] Patients receiving anti-inflammatory doses usually do not become symptomatic until they receive 6 g or more a day or achieve blood levels greater than 35 mg/dl.[2] The mechanism of toxicity is not well established in salicylate poisoning.[5] The ototoxic symptoms associated with anti-inflammatory doses can be readily reversed by decreasing the dose or discontinuing therapy.

Antimalarials

These agents have long been known to cause hearing loss and tinnitus when administered in large doses for prolonged periods of time (i.e. approximately 1 year). It is generally reversible and the mechanism for this ototoxicity is not known.[1,3] If it is anticipated that therapy will be prolonged with high doses then a base line audiogram and subsequent testing on a periodic basis should be considered.

Permanent congenital deafness has been reported with the use of quinine or chloroquine during pregnancy.[1,3] The manufacturer states that the benefits of drug use may outweigh the potential fetal toxicity.[14] Quinine should be avoided during pregnancy except in the treatment of uncomplicated chloroquine resistant P. falciparum.[15]

Summary

Drug induced ototoxicity is an iatrogenic disease that is not uncommon in the hospital setting. Each ototoxic drug or drug class is monitored somewhat differently and adherence to recommendations described above for avoiding or minimizing this adverse effect is strongly suggested. In addition, the clinician should be aware of those patients who are generally at an increased risk for ototoxicity. The University of Colorado defines these patients as follows:[16]

1. Patients with ototoxic drug(s) administered in the presence of renal failure.
2. Patients with an ototoxic drug administered in increased daily doses or for an extended period.
3. Patients with high peak or trough serum levels of ototoxic drug.
4. Patients receiving multiple ototoxic drugs concurrently or in consecutive courses (within 1 week).
5. Patients with pre-existing hearing loss or severe visual impairment or blindness.
6. Patients reporting ear symptoms (i.e. tinnitus, hearing loss, dizziness).

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Update: Acquired Immunodeficiency Syndrome—Europe

CENTERS FOR DISEASE CONTROL

As of Sept 30, 1985, 1,573 cases of acquired immunodeficiency syndrome (AIDS) were reported to the World Health Organization (WHO) European Collaborating Centre on AIDS by the 21 countries that correspond with the center. The new cases represent an average increase of 27 cases per week. Of the 1,573 patients, 792 are reported to have died, with a case-fatality rate of 50%.

The greatest increases in the numbers of cases were observed in the Federal Republic of Germany, 75 new cases (five to six new cases per week); France, 74 cases (five to six per week); the United Kingdom, 49 cases (three to four per week); and Italy, 42 cases (three per week). In each of the four countries—Belgium, the Netherlands, Spain, and Switzerland—an increase of one to two cases per week was noted. Five countries—Czechoslovakia, Hungary, Iceland, Poland, and the Union of Soviet Socialist Republics—had not reported any cases.

Distribution by Disease Category and Patient Sex

A total of 1,025 patients (65%) presented with one or more opportunistic infections; 309 (20%) had Kaposi's sarcoma (KS) alone; and 212 (13%) had opportunistic infections with KS. The category "other" (27 cases) includes four cases of progressive multifocal leukoencephalopathy (three cases in France and one case in Denmark); six cases of isolated cerebral lymphoma (two in the United Kingdom, three in France, and one in Switzerland); three cases of isolated Burkitt lymphomas of the brain (one in Denmark and two in the Federal Republic of Germany); ten cases of B-cell non-Hodgkin's lymphomas (four in the Federal Republic of Germany, three in the Netherlands, and one each in Luxembourg, Norway, and Switzerland); and four unknown cases in Sweden. The highest case-fatality rate (59%) was noted for patients with both KS and opportunistic infections. The case-fatality rate for opportunistic infections alone was 56%. For KS alone it was 25%.

Men accounted for 92% of the cases. The male-to-female ratio was 11:1. Forty-two percent of cases occurred in persons 30 to 39 years of age. Thirty-six pediatric cases (children younger than 15 years of age) have been reported in ten European countries. Twenty-four (67%) children either had parents with AIDS or parents in a group at high risk for AIDS; for ten pediatric patients (five with hemophilia and five who had blood transfusions), transmission was linked to contaminated blood or blood products. In two of the pediatric patients, no risk factor was reported.

Distribution by Geographic Origin

Total cases were distributed geographically and by risk group as follows:

Europeans* (1,330 cases [85% of total]).—A total of 1,288 (97%) patients were living in Europe before onset of the first symptoms; 42 (3%) were living in non-European countries including the United States (13); Zaire (12); Haiti (three); and one each in Bermuda, Brazil, Burundi, Congo, Gabon, Ghana, Malaysia, Morocco, Nicaragua, South Africa, Togo, and Venezuela; the country of residence was not specified for two patients.

Of the 1,330 European patients, 1,031 (78%) were homosexual or bisexual. Ninety (7%) patients were intravenous (IV) drug abusers, and 21 (2%), both homosexual and IV drug abusers. These 111 cases were diagnosed in Italy (45); Spain (26); the Federal Republic of Germany (14); France (11); Switzerland (seven); Austria (four); the United Kingdom (three); and Sweden (one). Fifty-two (4%) of the reported patients had hemophilia and were diagnosed in the Federal Republic of Germany (21); Spain (12); the United Kingdom (nine); France (three); Sweden (two); and one each in Austria, Denmark, Greece, Italy, and Norway. One German patient with hemophilia was reported as being homosexual and an IV drug abuser. Thirty (2%) patients, for whom the only risk factor found was blood transfusion, were diagnosed in France (15); Belgium, the Netherlands, and the United Kingdom (four each); the Federal Republic of Germany (two); and Italy (one). Among these 30 cases, five had received blood transfusions outside Europe. One who was diagnosed in the Netherlands had undergone heart surgery in the United States; another, diagnosed in France, had received blood transfusions in Haiti and Martinique; and two diagnosed

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—*Morbidity and Mortality Weekly Report*, February 14, 1986/Vol. 255, No. 6

in Belgium had received transfusions in Zaire. One child diagnosed in the United Kingdom had received a blood transfusion in the United States. For 90 patients (7%), no risk factor was found (male:female ratio, 2:1). Risk-factor information was not obtained for 16 patients.

Caribbeans (39 [2%]).—Thirty-seven patients were living in Europe before the onset of the first symptoms. Thirty-two Haitians were diagnosed in France; one in Belgium; and one in Switzerland; one Dominican and one Jamaican were living in the United Kingdom; one patient of unspecified origin was living in Switzerland. Two Haitian patients diagnosed in France were living in Haiti.

Of the Caribbean patients, four were homosexual, and no risk factors were identified for 34 (male:female ratio, 3:1). Risk-factor information was not obtained in one case.

Africans (157 [10%]).—These persons were diagnosed in eight European countries and originated from 22 African countries (63% from Zaire and 10% from the Congo). Among the remaining 20 countries, the number of cases varied from one to five. Eighty-six patients (55%) were living in Europe before onset of the first symptoms. Sixty-six resided in Africa and one lived in the United States. Two patients from Zaire and one each from Burundi and Rwanda were living in other parts of the world.

Of the 157 Africans, 11 were homosexuals; five had received blood transfusions; and one was both homosexual and an IV drug abuser. No risk factors were identified for 124 persons (male:female ratio, 2:1); and for 16 patients, information was not obtained.

Other Origins (47 cases [3%]).—Most of these patients originated from the American continents: the United States (23); Argentina (four); Brazil (three); and one each from Canada, Chile, Nicaragua, Peru, and Uruguay. One patient each originated from Australia, Egypt, Lebanon, New Zealand, Pakistan, Thailand, and Turkey; the origins of four were unknown. Fourteen of these patients were not living in Europe before the onset of the first symptoms (ten in the United States; one each in Canada and Africa; and the locations of two were unknown).

Among the 47 patients, 39 were homosexual; two were both homosexual and IV drug abusers (one Canadian diagnosed in the United Kingdom and one American diagnosed in Spain). One American diagnosed in Sweden had hemophilia. Two did not present any risk factors. Information was not obtained in three cases.

Distribution by Risk Group

It is not possible to compare precisely the situations in the various European countries because of differences that may exist in the methods of data collection. Furthermore, in countries were AIDS is still rare, distribution may be modified with the increase in number of cases. However, some observations can be made:

Homosexual men.—Patients with AIDS belonging to this risk group accounted for 60% to 100% of the total number of cases in 12 of 16 countries. In four other countries (Belgium, Greece, Italy, and Spain), homosexual men accounted for fewer than 50% of cases.

Intravenous drug abusers.—The spread of AIDS in Europe has been particularly marked in this group. In October 1984, IV drug abusers represented only 2% of the total number of European cases and were reported by three countries. By Sept 30, 1985, they represented 8% of all European cases and were reported by nine countries, a significant increase ($P<0.001$). Italy and Spain together accounted for 63% of the IV drug abusers with AIDS in Europe. Forty-five (49%) of the 92 Italian patients and 23 (37%) of the 63 Spanish patients were members of this risk group.

Cases related to transfusion of blood and blood products. Ten countries have reported AIDS among patients with hemophilia, and six have reported cases among recipients of blood transfusions.

Patients not belonging to any of the above risk groups.—This group contributed the second largest number of cases. In four countries (Belgium, France, Greece, and Switzerland), a high proportion of patients originated from regions where most AIDS patients have not belonged to any of the above risk groups but where heterosexual transmission is thought to be a major factor. (In Belgium, 72% of the patients originated from equatorial Africa; in France, 11% originated from the same region, and 8% from Haiti; in Switzerland, 12% originated from equatorial Africa.)

Editorial Comments by the WHO Center

Prevention of AIDS transmission through blood transfusion is now effective in most European countries because of systematic screening for HTLV-III/LAV antibodies in blood donors. Even in countries where no cases of AIDS have been officially reported, the establishment of screening programs is being studied; in Hungary, screening is already compulsory.

As in the United States, homosexual men account for the highest percentage of the total number of cases (69%). The distribution by risk group shows a marked increase in cases among drug abusers, accounting for 2% of 421 European cases by July 1984, and 8% of the 1,573 cases reported by September 1985. More than 40% of the cases in Italy and Spain occurred in this group. Several 1985 studies in various European countries showed a high frequency (20% to 50%) of serologic markers of infection with HTLV-III/LAV in IV drug abusers, indicating that the spread of the infection has been rapid in this population. Information campaigns that are being set up should emphasize this aspect of the spread of AIDS.

REFERENCE

1. CDC: AIDS weekly surveillance report. Sept 30, 1985.

The President's Page

Control and a Special Identity

The Garvey Health Care Consultants Group has submitted an interim report suggesting that a financially viable strategy *can* be developed to establish a Statewide CSMS IPA/HMO.

Preliminary findings reveal that physicians are confused and apathetic towards IPA/HMO's. An aggressive educational program will be necessary to define the advantages and absolute necessity for establishing a CSMS statewide IPA/HMO at this time. Simultaneously, Connecticut employers are as confused as the physician community about the future of IPA/HMO's. The HMO movement is entering a new stage of maturity where competition is becoming more aggressive. The novelty is over! Employers are becoming more selective, and competing HMO's will be required to demonstrate very unique differential values to obtain contracts in the future. Finally, the insurance regulators of the State thus far have indicated that licensure will depend upon whether or not a future HMO is significantly capitalized and is composed of an organized majority of office based physicians throughout the State.

Presently, there are nine operational HMO's in the State, and four additional firms will enter the scene in the next six months. By 1990, 25% (or 790,000) State residents will be enrolled in a pre-paid health plan. We can expect additional monopolistic combinations of independent business enterprises to enter the marketplace in the future. In spite of the aforementioned, remember that physicians are congenital competitors. We are not too late in setting up our own Statewide IPA/HMO.

It is time for the physicians of this State to create sanity in a mad world of commercial venturism. Heretofore, physician's services have been exploited by fiscal intermediaries for their own financial gain. By forging an organization which is owned, managed, and controlled by physicians, profits previously realized by the intermediaries will be returned to our organization to improve the delivery of care and to maintain a competitive edge. It should be an organization which converts the system back to the main concern of caring for the patient.

A new trend is developing. Industry and employers are becoming increasingly refractory to the parade of faceless look-alike HMO's that lack data on the quality performance of their organization. HMO's of the future will have to distinguish themselves based on a high standard of performance as well as cost effectiveness. Our survival will be based on a special identity. We have the opportunity to provide for a very special identity. In order to achieve this identity, we must embody within the organization all of our personal ideas and ideals for which we have stood individually in the past. In addition, we must be prepared to "police" ourselves, to conduct realistic quality review, and be willing to accept a reasonable reimbursement for our services. Finally, and most important of all, the key to the success of this corporate endeavor will be *control.*

In conclusion, we must be ever mindful of the thundering hoof beats of the giant medical cartels whose grand design is to turn individuals into mere human laboring mechanisms. We must prevent ourselves from being turned into "someone else's creation." Each of us must establish a separate peace as we transform our personal expectations and philosophies into the statewide corporate effort.

The final word is that survival will depend upon *control and a special identity.*

William A. Whalen, M.D.
President

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Reflections on Medicine

Logan Clendening
1884-1945

ROBERT U. MASSEY, M.D.

Logan Clendening has been gone for more than 40 years; except for those with a special devotion to old medical books or the history of medicine, his name is now little known beyond the precincts of the University of Kansas Medical Center.

When I was nine years old, my favorite aunt, knowing of my recent decision and by then firm determination to pursue a career in orthopedic surgery, presented me with a copy of Clendening's *The Human Body* for Christmas. I'm sure she had not read it through; if she had, in spite of her liberated 1920s view of such things, she might have considered some of his robust humor a little less than suitable for a fifth grader. In the chapter on the "General Biology of Reproduction and Sex," he describes a scene from *The Painted Veil* by W. Somerset Maugham to illustrate the difference between the ways in which male and female "look at the phenomenon of existence," especially the business of keeping up the world's population. The male, he writes, "is expressly made to roam over the earth impregnating as many females as he possibly can. It is the deepest instinct in his heart, except the instinct for self-preservation. It is the deepest desire of nature, or if you prefer the term, the deepest desire of God." Then he adds: "The only thing that can control him is the common sense of the female. The sense to lead him to the altar . . . , the sense to use the means her old mothers fashioned for her to bind him with hoops of steel."

"And all these things, I think, I should tell to everyone's daughter. Except for the sly fact that she knows them already."

He writes of his discomfort when parents "send me their children at about the age of adolescence in order that I may explain to them what is called the secrets of life."

"When I attempt to elaborate some of my reticenses, the parents protest that unless the children learn it from me, they will learn it in the gutter. My reply to that is: 'The gutter is a very good school.' I am myself a matriculate from the gutter . . . . They teach this particular subject very well in the gutter . . . with conviction and an inescapable clarity of detail, and with just sufficient of that gorgeous air of secrecy to invest it with the dubiousness of a speculation. In the gutter, best of all, they teach it as a joke. Which is just what it is . . . . It is the master joke of the universe. It is so magnificent a joke that the very stars rock with the echo of the laughter which it arouses."

The joke, of course, was meant to be on the male; what had begun as a playful conquest was to turn into a binding obligation: "And the hoarse chuckle of Mother Nature and Mother Church is heard in the wings." Now, 60 years later, the joke has gone stale; an indulgent welfare state has lifted the boy's heavy burden of reponsibility; he is free to roam and she to receive the plaudits of her silly friends watched over by a protecting society eager to comfort and too unsure of its grounds to define or enforce its rules.

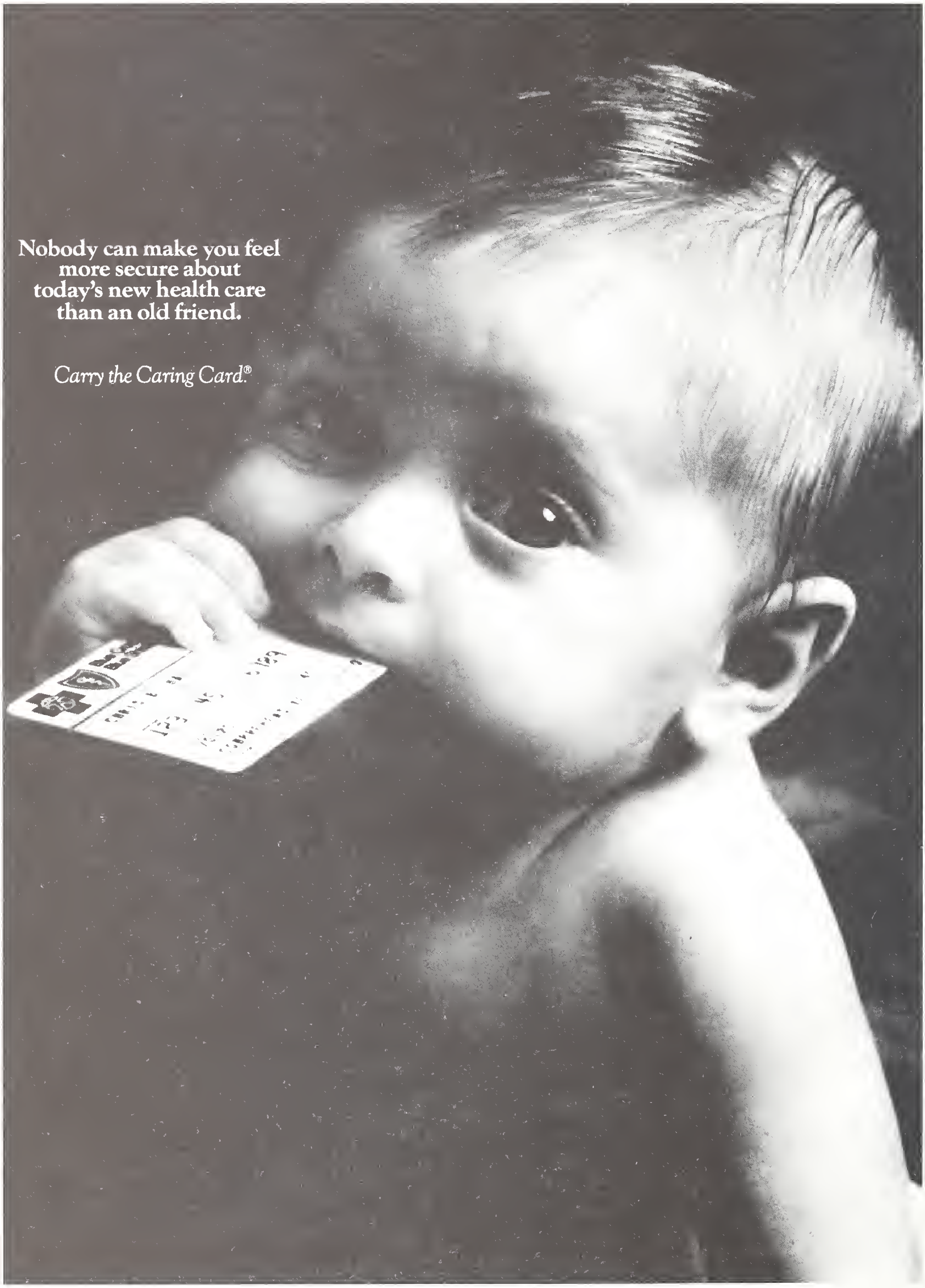
I learned to name all the major bones and muscles, acquired some knowledge of anatomy and physiology, and best of all, came to recognize the names of Vesalius, Harvey, Auenbrugger, Beaumont, Jenner, Withering, Laennec, Pasteur, and Koch, and most impressive at that time to me, W.G.T. Morton and John Collins Warren. I remember telling the story of the discovery of ether anesthesia to my classmates, and for years after recounted that dramatic "Gentlemen, this is no humbug" tale exactly as Clendening had written it, even getting some facts wrong, just as, I believe, he did.

I have recently reread much of *The Human Body* as well as Ralph Major's brief biographical sketch from 1958. "His wit was proverbial," Major writes, "but it did not have a sting or an unpleasant aftertaste. He was essentially tender and kind hearted . . . ."

If memory after 55 years can be counted upon, I felt again what I had sensed then—Clendening's joy in living, his delight that he had been privileged to be a physician, a teacher, an historian, very like, I now think, the joy expressed by Rat in Kenneth Grahame's *The Wind and the Willows.*

" 'Nice? It's the only thing,' said the Water Rat solemnly, as he leaned forward to his stroke, 'Believe me, my young friend, there is *nothing*—absolutely nothing—half so much worth doing as simply messing about in boats.' " "Or in medicine," Logan Clendening would surely have added.

ROBERT U. MASSEY, M.D., Professor and Head of the Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.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Editorial

Silence Is Assent

At a time when we are becoming used to the fact that all avenues of the media have given significant attention to the alleged misdeeds of the medical profession, we now come face to face with some remarks made by one of our own otherwise highly regarded physicians. I have received several letters and much personal comment regarding the way that the media has seized upon the article written by Dr. Arnold Relman, Editor of *New England Journal of Medicine* which deals with incompetent physicians and medical malpractice.

I have two very strong objections to Dr. Relman's stated position. The first of these is the fact that the percentage degree of incompetence of physicians has been an assumption on Dr. Relman's part with very little reasoning as to how he arrived at this remarkable figure estimated to be 20,000 to 30,000 impaired physicians. A second objection is even more grievous since it is totally lacking in any supporting data. The fact is that statistics show that the diligent, clinically busy, practitioner (especially including those of senior status, from the private sector and academia, etc.) are the ones being sued. The relationship between incompetency and malpractice has never been strongly made, to my knowledge, yet Dr. Relman uses the phrase several times that "I suspect" and "my suspicions" with the most threadbare supposition backing these "suspicions" up. Amongst other vicious attacks on the medical profession, Mr. Andrew Stein of the *New York Times* wrote an editorial entitled "Doctors Who Get Away with Killing and Maiming Must be Stopped." Naturally, he quotes Dr. Relman's article. Congressmen (and former astronaut) John Glenn proposed a populist type legislation based on this same assumption. Dr. Relman makes it sound ridiculously easy for an errant physician to simply move to another locale to avoid censure. The *New Haven Register* seized upon this national action to join in with this particular wolf pack. Frankly and immodestly, I must state that I have been personally involved in the credentialing and ethical matters of medicine on a very active basis during frequent episodes in my 31 years of private practice. Having been honored by being president of the New Haven County Medical Association, chief of staff on different occasions and for over 25 years being chief of a clinical department in a community hospital along with many other state committee duties, I have something more than a "suspicion" to report. What I have to report is that the ethical standards and the medical competence of my colleague practitioners is indeed extremely high. (If only it were this way in other professions!!) Seven in ten attorneys say they'd report a lawyer outside their firm who acts unethically, and three in five would turn in a colleague in their own firm, according to the *American Bar Association Journal.* Since 71% admit they've encountered a dishonest opposing counsel, you'd expect them to be doing a lot of whistle blowing. Not so. The ABA Center for Professional Responsibility says the vast majority of misconduct complaints are initiated by clients or peer reviewers; lawyers and judges rarely report a colleague. Society, as well as our own profession, expects more of us and thus these ABA figures mean little here, except that the media will probably give it little notoriety. I have more than a "suspicion" that the searching out of details regarding the applicant's training and credentials is carried out at all levels, hospital, local and county medical societies, state and specialty societies.

Dr. Relman points the finger in particular at specialists. Most specialists require hospital appointments and as most of our readers know, it is practically im-

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself responsible for statements made by any contributor.

possible to circumvent this system of in depth review of qualifications. Despite the fact that the FTC and other legal manipulators have made it more difficult to effectively criticize our erring colleagues or reduce their privileges or appointments, the process still works. Not only the doctors, but the hospital lay authorities are very conversant with what happens when there is a bad outcome which could in any way be related to the falsely credentialed or incompetent physician. Thus, they have also insisted on tight credentialing procedures.

Dr. Relman properly presents the fact that many states, hospital authorities, specialty societies, etc. require recertification of their training. The AMA recognition award is still another of many examples of how medicine continues to "pull itself up by the bootstraps." Unfortunately, the media has omitted any discussion of any portion of this aspect of Dr. Relman's article. He does state that "the overwhelming majority of practicing physicians in this country are competent and conscientious." Too many other aspects of this article demean this position. Although Dr. Relman indeed comments on the increasingly large number of physicians as a factor, I believe that he fails to take into account that there are some beneficial effects of larger numbers of physicians in this arena. Due to the competitive situation developed within the medical community, many hospitals have closed their staff except to the most highly qualified people. Specialists in a particular field are not apt to credential some newer person in his field unless he meets extremely high standards. In a choice amongst qualified applicants, the highest qualified is usually chosen. Another controlling factor with increased M.D.s is that indeed the "marketplace" eliminates a number of doctors who do not match up to the expectations of not only their patients but their colleague physicians.

In a recent informal survey, it was learned that 60% of our obstetricians in the recent past had either threatened or actual law suits against them. Are we to believe that these are 60% incompetent physicians? He implies that, because many cases are settled without trial, that these doctors go unscathed who are truly "guilty." The legal system has been made so expensive to fight to win such suits, it has proven to be a true Pyrrhic victory. (This has been recently demonstrated in the case of the copper 7 IUD situation. In this instance, this device, which had gained quite high marks for its safety and effectiveness, was simply withdrawn by G.D. Searle and Co. because to fight and win (which they did) became too costly in an area where there are limited profits.) Most all of us know parallel examples.

He concludes this article with a group of suggestions which are pretty much self-evident and not particularly helpful to this situation.

The present tort system cannot go on forever in its present status. In only a few years, I feel we will look back at these "dark ages" and wonder why we could not have arrived at an equitable system sooner. Such system could give early, appropriate settlement to the patient without the expenses and delays of our present system. Concomitantly, the medical profession must maintain and increase its peer review and credentialing process at an even higher level.

Stewart J. Petrie, M.D.
Editor Pro tem

In the process of writing this editorial, I have received many comments, verbally and in writing, speaking to these main points, hopefully brought out in the editorial. My thanks go to the many people who have shown interest in this heated topic.

Obesity and Television Viewing

Dietz and Gortmaker investigated the association between television viewing and obesity in children by examining data from the National Health Examination Survey. The sample included 6,965 children from six to 11 years of age, studied in 1963 to 1965, and 6,671 children from 12 to 17 years of age, studied in 1966 to 1970. The group of children studied in the latter period included 2,153 children who had been studied in the first period.

A significant association was found between the time spent watching television and the prevalence of obesity. In the 12- to 17-year-old age group, the prevalence of obesity increased by about 2 percent for each hour of television viewed per day. A previous history of obesity was the only factor that had a larger independent effect than television on the prevalence of obesity. Obese and nonobese children did not differ with respect to the amount of time spent alone, the amount of time spent with friends or the time spent on other leisure activities. Obese children were not considered to be more passive, withdrawn or isolated than nonobese children. The association between obesity and television watching persisted when controlled for a variety of variables, including previous obesity, season, region, population density, race and socioeconomic class.

Possible measures for preventing obesity in television watchers include altering the frequency of television viewing, decreasing food consumption while watching television or reducing consumption of foods advertised on television, which tend to be high in calories. (*Pediatrics*, May 1985, p. 807.)

Letters to the Editor

LOST SAUERBRUCH RECEPTORS

To the Editor: I was most interested in Dr. Robert Massey's article in the December 1985 issue of *Connecticut Medicine* concerning "Brain Receptors."

I find it sad that it is only since last spring that Dr. Massey has come across the name of Professor Ferdinand Sauerbruch. It would seem to me that these Sauerbruch receptors should have been there years ago.

Professor Sauerbruch was one of the most renowned thoracic surgeons that ever lived. His life was indeed intriguing and most tragic. His contributions to thoracic surgery, German surgery and teaching were of the highest quality. I would like to comment a bit on Sauerbruch's life and to some statements that Dr. Massey made.

Aside from his membership in the Mittwoch-Gesellschaft, Professor Sauerbruch was also responsible for getting Jewish physicians out of Germany in 1933. Many of these physicians were sent to Turkey to help the Turkish government revamp their medical facilities. Sauerbruch's chief assistant, Dr. Rudolf Nissen, himself a world-renowned surgeon, went to Ankara and then to New York.

A more intimate and honest view of Professor Sauerbruch is found in Nissen's Memoirs, *Helle Blätter, Dunkle Blätter* (The Bright Side and the Dark Side).[1] The reader will learn that Sauerbruch suffered throughout his life with a severe manic-depressive illness. This was both untreated and unrelenting. In the 1940's he furthur developed cerebral arteriosclerosis which caused him great embarrassment in his surgical judgments. After the war, the East Germans continued him as their Chief of Surgery at Charite Hospital in Berlin, but his deteriorating condition caused the DDR to relieve him of his position. Nevertheless, he continued to operate in his own apartment in Berlin. His mental condition was so deteriorated that his retirement ended in humiliation and great chagrin.

Dr. Massey's reference to King George V is a classic story. German newspapers for years depicted cartoons of Sauerbruch hauling his riches off to the bank. Professor Sauerbruch treated Kings, Queens, high government officials and wealthy business people. He was rewarded accordingly. What is not known is that he treated thousands of indigent patients, giving much time and energy to them. He was adored and revered by all of his patients.

The reference to Professor Sauerbruch's autobiography deserves comment. Nissen, who probably was closer to Sauerbruch than any other doctor, claims in his book that Sauerbruch did not write this book—that after a few brief discussions with the famous professor, a German journalist did it all.

Regarding Professor Forssmann's gripe concerning his rejection by Sauerbruch, there are conflicting points here. Sauerbruch was a true authoritarian and a tyrant with his staff. He could be unrelenting and brutal and he was not impressed with Forssmann's credentials. Dr. Forssmann suffered later in his life because of his many flirtations with the Nazis. I refer those interested to Forssmann's autobiography.[2]

Professor Sauerbruch's life was one of genius and tragedy. His textbook of Thoracic Surgery is still a classic. He lectured in over 50 countries and treated royalty in all of them. He was a fantastic teacher and a great contributor to the field of surgery. He was also controversial and dictatorial. He held back anesthesiology in Germany for 25 years by failing to recognize it as a separate specialty.

Professor Sauerbruch certainly is on the same plane as Harvey Cushing and Michael DeBakey. It is sad that so little is remembered about this German speaking physician. Perhaps it is due to the language barrier or perhaps it is political. Nevertheless, I am glad that Dr. Massey's Sauerbruch receptors are at least forming at this point in time.

Bennett I. Enowitch, M.D., M.P.H.

Hartford, CT

1. Nissen, Rudolph. Helle Blätter, Dunkle Blätter. Deutsche Verlag Anstalt: Stuttgart, 1969.
2. Forssmann, Werner. Experiments on Myself. St Martin Press: New York, 1974.

The above letter was referred to the author of the article who offers the following reply.

To the Editor: I am grateful to Dr. Enowitch for additional information concerning Professor Ferdinand Sauerbruch. While his name as a pioneer in thoracic surgery was not entirely new to me, the details of his life attracted my interest even more since I began to review the published minutes of the *Mittwoch-Gesellschaft.*

I am relieved, and not surprised, to learn that Professor Sauerbruch may not personally have been entirely responsible for his autobiography. The publisher's note to the English translation, *A Surgeon's Life,* includes this statement:

> "After most careful and systematic enquiries in Germany, it has been established beyond doubt that the greater part of these memoirs were recorded by Professor Sauerbruch on a tape-recorder and the rest dictated by him. He read and approved *almost* (italics mine) the whole of the German text before his death."

This would suggest that Nissen's claim that Sauerbruch was not the author may be substantially correct, especially since his memoirs were published in the year of his death (1951), after, according to Dr. Enowitch, a period of mental deterioration presumably the result of cerebral arteriosclerosis.

I am sure that Dr. Enowitch is better able to judge whether some of the more unusual and flamboyant episodes described in the autobiography are the products of Professor Sauerbruch's manic-depressive illness rather than accurate portrayals of reality. Frau Doctor Mathilde Ludendorff in a 1952 letter published as an appendix insists that some of his anecdotal passages concerning her husband, General Ludendorff, were untrue: "I am sure that, had the writer seriously thought them over, he would have told a different story."

I have located a copy of *Helle Blätter, Dunkle Blätter* and am prepared to bind a few more Sauerbruch receptors!

Robert U. Massey, M.D.

Farmington, CT

NOTICE TO CONTRIBUTORS

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult INFORMATION FOR AUTHORS. This material may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

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194th ANNUAL MEETING
# of the
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May 7, 8, 1986
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A MESSAGE FROM THE PRESIDENT

As President, I invite and urge all members of the Society to participate in the 194th Annual Meeting of the Connecticut State Medical Society.

HMOs, IPAs, DRGs, and the PPS are already facts of life, and with the ever increasing changes in the practice of medicine, due to the malpractice insurance crisis, medicare freeze, etc., it would seem that this year's meeting of the House of Delegates on May 7 should prove of special interest to all Connecticut physicians. Members can observe their elected representatives in action, doing their best to deal effectively with the rapidly changing legislative, economic and social issues of the day in relation to the care of the patient. They, also, will have a chance to express their own views in the reference committee hearings held during the morning session of the House. Most of the business of the House is discussed at reference committees and the membership-at-large should take advantage of this opportunity to participate in these hearings.

The inauguration of the new President, Joseph C. Czarsty, M.D., of Oakville, will take place at the House of Delegates meeting and will be followed by a reception for the President immediately following the close of the meeting.

An excellent and timely scientific program has been arranged on Thursday, May 8, on new therapeutic advances and also on the issue of informed consent, which should be of interest to all physicians. It is also an opportunity to obtain your CME credits.

Section meetings will meet on May 8 and will offer programs of special interest.

Your Society plans these programs for you, and it is hoped that you will make every effort to participate in your Society's activities.

William A. Whalen, Jr., M.D.

GENERAL INFORMATION
READ CAREFULLY

REGISTRATION

The registration desk will be located on the mezzanine floor of the hotel and everyone attending the meeting is requested to register. There will be no charge for registration and all members of the Society will be given a guest luncheon ticket *only* if they register.

PARKING

There are parking facilities at the hotel and in the immediate surrounding area.

TELEPHONE

Telephone messages will be received at New Haven, 772-1700.

LUNCHEON

Luncheon will be served in the ballroom on the mezzanine floor and ALL MEMBERS OF THE SOCIETY REGISTERING WILL BE THE GUESTS OF THE SOCIETY. PLEASE REMEMBER A LUNCHEON TICKET WILL BE GIVEN TO MEMBERS ONLY IF THEY REGISTER.

HOTEL ACCOMMODATIONS

Persons who wish to stay overnight at the hotel should make room reservations as soon as possible. Please indicate in your letter that you are attending the Connecticut State Medical Society Meeting.

PROGRAM

The House of Delegates will be held on May 7th and the scientific program will be held on May 8th. The scientific program will be concentrated in one day, May 8th. The general program will be held in the ballroom between 10:30 A.M. and 4:00 P.M. and the section meetings will be held in the morning at 8:30 A.M. and in the afternoon at 4:00 P.M. in the rooms listed in the program.

PRESIDENTS INAUGURATION

The inauguration of the new President will take place at the House of Delegates meeting on May 7th at about 3:00 P.M. All members are invited to attend the inauguration. A reception for the President will be held immediately following the close of the meeting.

EXHIBITS

All the exhibits will be located on the mezzanine floor. Physicians should take advantage of the opportunity to review what is new and timely by visiting the commercial exhibits.

ALL ACTIVITIES WILL TAKE PLACE AT THE HOTEL UNLESS OHTERWISE INDICATED

HOSPITAL RESIDENTS, INTERNS AND MEDICAL STUDENTS ARE CORDIALLY INVITED TO ATTEND THIS MEETING.

ANNUAL MEETING OF THE HOUSE OF DELEGATES
WEDNESDAY, MAY 7, 1986
BALLROOM MEZZANINE

Presiding:

Lawrence B. Ahrens, M.D., Wethersfield, Speaker of the House

Mehdi S. Eslami, M.D., Waterbury, Vice Speaker of the House

9:30 REGISTRATION OF DELEGATES

10:00 CALL TO ORDER
REPORTS OF OFFICERS, COMMITTEES, OTHERS
OLD AND NEW BUSINESS
REFERENCE COMMITTEE HEARINGS

1:00 LUNCHEON—PRESENTATIONS AND AWARDS
Guest Speaker—William D. Logan, Jr., M.D. President, Georgia Medical Association

2:30 CALL TO ORDER
REPORT OF AUXILIARY TO CSMS
ADDRESS OF THE PRESIDENT—WILLIAM A. WHALEN, Jr., M.D., WILLIMANTIC
ELECTION OF OFFICERS AND COMMITTEES
INAUGURATION OF THE NEW PRESIDENT—JOSEPH C. CZARSTY, M.D., OAKVILLE
INAUGURAL ADDRESS
AWARD TO PAST PRESIDENT
REFERENCE COMMITTEE REPORTS
INTRODUCTION OF GUESTS
ADJOURNMENT
RECEPTION TO FOLLOW

GENERAL SCIENTIFIC PROGRAM
THURSDAY, MAY 8
MORNING SESSION

8:15 REGISTRATION—MEZZANINE

8:30-10:00 MEETINGS OF SECTIONS OF THE SOCIETY
(Listing elsewhere in program)

10:00 INTERMISSION TO VISIT EXHIBITS

BALLROOM WEST

10:20 CALL TO ORDER AND WELCOMING REMARKS
JOSEPH C. CZARSTY, M.D., OAKVILLE
President, Connecticut State Medical Society

10:25 INTRODUCTIONS: Franklin Robinson, M.D., New Haven

Presiding:
Norman J. Marieb, M.D., *New Haven*

10:30 ENDOSCOPIC LASER THERAPY FOR HEMORRHAGIC LESIONS OF THE GASTROINTESTINAL TRACT
NELSON A. BONHEIM, M.D., GREENWICH; Assistant Attending, Greenwich Hospital; Assistant Clinical Professor of Medicine, Yale University School of Medicine.

10:50 ENDOSCOPIC LASER THERAPY FOR GASTROINTESTINAL TUMORS
JAMES W. WOOD, M.D., GREENWICH; Senior Attending Physician, Greenwich Hospital; Assistant Clinical Professor of Medicine, Yale University School of Medicine.

SYMPOSIUM ON OSTEOPOROSIS

11:10 ESTROGEN REPLACMENT THERAPY—THE PRO'S AND PRO'S
BURTON V. CALDWELL, M.D., NEW HAVEN; Associate Professor Clinical Medicine (Endocrinology), Yale University School of Medicine; Staff Physician, Hosptial of St. Raphael and Yale-New Haven Hospital.

11:50 NON-INVASIVE METHODS FOR BONE MINERAL ASSESSMENT
DAVID J. SARTORIS, M.D., SAN DIEGO, CALIFORNIA; Assistant Professor of Radiology, University of California School of Medicine, San Diego; Attending Staff, Musculoskeletal Radiology Section, University of California Medical Center.

12:30 INTERMISSION TO VISIT EXHIBITS

1:00 LUNCHEON

AFTERNOON SESSION

Presiding: Franklin Robinson, M.D., *New Haven*

SYMPOSIUM ON THE MANY FACETS OF INFORMED CONSENT

2:00 THE TREATING PHYSICIAN'S VIEW OF INFORMED CONSENT
GEORGE ROBINSON, M.D., BRONX, NEW YORK; Professor of Surgery (Cardiothoracic), Albert Einstein College of Medicine; Chief, Cardiothoracic Surgery, Montefiore Hospital.

2:20 PRIMER ON INFORMED CONSENT FOR CONNECTICUT PHYSICIANS
J. MICHAEL EISNER, ESQ., NEW HAVEN; Partner, Wiggin and Dana.

2:40 ARE "MIRACLES, MYSTERY AND AUTHORITY" BETTER MEDICINE?
JAY KATZ, M.D., NEW HAVEN: John A. Garver Professor Law and Psychonalysis, Yale Law School; Attending Psychiatrist, Yale-New Haven Hospital.

3:00 PANEL DISCUSSION

3:30 INTERMISSION TO VISIT EXHIBITS

4:00 MEETINGS OF SECTIONS OF THE SOCIETY
(Listing elsewhere in program)

THURSDAY, MAY 8
MEETINGS OF SECTIONS OF THE SOCIETY
MORNING SECTION PROGRAMS

SECTION ON FAMILY PRACTICE

8:30 A.M. Harborside Room, Top of the Park

President: Neil H. Brooks, M.D., *Rockville*
Secretary: John M. Greeley, M.D., *Stamford*

BUFFET BREAKFAST HONORING THE INSTALLATION OF JOSEPH C. CZARSTY, M.D., AS PRESIDENT OF THE CONNECTICUT STATE MEDICAL SOCIETY.

The breakfast is being sponsored by the Section and the Connecticut Academy of Family Physicians and is open to members of these organizations and invited guests.

SECTION ON PHYSICAL MEDICINE

8:30 A.M. Trianon Room

President: Jerrold N. Rosenberg, M.D., *New Haven*
Secretary: Francis X. Palermo, M.D., *Wallingford*

8:00 REGISTRATION AND COFFEE

8:30 WELCOME—Terry Edelstein, Executive Director, Connecticut Association of Rehabilitation Facilities.

Jerrold N. Rosenberg, M.D., President, Section on Physical Medicine

8:45 FUNCTIONAL AND ELECTRICAL STIMULATION ON IMPLICATIONS FOR CONDITIONING, WALKING AND UPPER EXTREMITY FUNCTION
Philip Arnold, M.D., Director of Physical Medicine and Rehabilitation, Newington Childrens Hospital

9:45 COFFEE BREAK

10:00 SYMPOSIUM ON PROSTHETICS AND ORTHOTICS—AN UPDATE
Mr. William Farrell, Prosthetist
Michael Collins, M.D., Gaylord Hospital, Wallingford
Arlen Lichter, M.D., Waterbury Hospital, Waterbury

11:00 ENVIRONMENTAL CONTROL SYSTEMS—AUGMENTED COMMUNICATION
Patrick Demasco, M.S., Boston Research Engineer, Tufts New England Medical Center.

SECTION ON PREVENTIVE MEDICINE

8:30 College Room A

Chairman: J. Howard Johnston, M.D., *West Hartford*

LIFE (WITH OR WITHOUT) STYLE
C. CRAIG WRIGHT, M.D., STAMFORD: Director of Health Services, Xerox Corporation

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AFTERNOON SECTION PROGRAMS

SECTION ON ALLERGY

6:00 P.M. Governor Eaton Suites A & B

President: David M. Zolov, M.D., *Danbury*
Secretary: Anthony V. Piccirillo, M.D., *Wallingford*

6:00 SOCIAL HOUR

6:30 DINNER—
Guest Speaker—MARK I. OESTRICHER, M.D., TRUMBULL
Title: "DERMATOLOGIC ASPECTS OF ALLERGIC DISEASE"

SECTION ON ANESTHESIOLOGY

4:00 P.M. Summit Hotel, Hartford

President: William D. Conrad, M.D., *Hartford*
Secretary: Gerald G. Piserchia, M.D., *Hartford*

MISHAPS IN ANESTHESIA—A STRATEGY FOR THEIR PROTECTION
RICHARD J. KITZ, M.D., BOSTON; Professor and Chairman, Department of Anesthesia, Harvard Medical School

SECTION ON DERMATOLOGY

12:00 Noon Plaza Room

President: Laurence A. Sibrack, M.D., *Danbury*
Secretary: Jeffrey N. Alter, M.D., *Waterbury*

12:00 LUNCHEON—
Guest Speaker—RICHARD L. EDELSON, M.D., NEW HAVEN; Professor and Chairman, Department of Dermatology, Yale University School of Medicine
Title: "FUTURE TRENDS IN DERMATOLOGY"

SECTION ON GASTROENTEROLOGY

5:00 P.M. Gaetano's Restaurant, Hartford

President: Howard L. Taubin, M.D., *Stratford*
Secretary: James W. Innes, M.D., *Greenwich*

5:00 THE NEW 5-ASA DELIVERY SYSTEMS
GERALD FRIEDMAN, M.D., NEW YORK; Associate Professor of Medicine, Mt. Sinai School of Medicine

DINNER TO FOLLOW

SECTION ON NEUROSURGERY

4:00 P.M. College Room A

President: Alvin D. Greenberg, M.D., *New Haven*
Secretary: Dennis D. Spencer, M.D., *New Haven*

A PHILOSOPHY AND SYSTEM TO MAKE MICROSURGERY EASIER
I. MELBOURNE GREENBERG, M.D., NEW YORK; Associate Clinical Professor of Neurological Surgery at Stoneybrook School of Medicine, Long Island

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SECTION ON OBSTETRICS AND GYNECOLOGY

4:00 P.M. Trianon Room

President: Edwin J. T. Moore, M.D., *Waterbury*
Secretary: Samuel G. Smith, M.D., *Manchester*

4:00 TEEN PREGNANCIES, ARE THERE SOLUTIONS?
VICTOR C. STRASBURGER, M.D., BRIDGEPORT; Department of Adolescent Medicine, Bridgeport Hospital

BUSINESS MEETING

5:30 SOCIAL HOUR AND DINNER—
HARBORSIDE ROOM, TOP OF THE PARK

SECTION ON PATHOLOGY

4:00 P.M. Governor Eaton Suites D & E

President: Edwin M. Clayton, M.D., *New London*
Secretary: Jack Hasson, M.D., *Hartford*

1986 UPDATE ON REGULATIONS AND REIMBURSEMENT ISSUES IN PATHOLOGY
WILLIAM T. PASTUSZAK, M.D., HARTFORD; Chairman, Professional Reimbursement Committee, Connecticut Society of Pathologists

MR. ROBERT TESSIER, HARTFORD; Senior Reimbursement Consultant, HBP Services, Inc.

POSTGRADUATE PHYSICIAN SECTION

4:00 P.M. College Room E

BUSINESS MEETING

ELECTION OF OFFICERS
(All Hospital residents invited to attend this meeting.)

SECTION ON PROCOTOLOGY

4:00 P.M. College Room B

President: Bernard J. Kaplan, M.D., *Hartford*
Secretary: Sanford Savin, M.D., *Bridgeport*

BUSINESS MEETING

ELECTION OF OFFICERS

STUDENT MEMBER SECTION

4:00 P.M. College Room D

Co-Presidents: Eric F. Bernstein, *Yale*
B. Theo Mellion, *U. Connecticut*

BUSINESS MEETING

ELECTION OF OFFICERS
(All medical students invited to attend this meeting.)

SECTION ON UROLOGY

4:00 P.M. College Room C

President: James F. Walsh, III, M.D., *Bridgeport*
Secretary: Haik Kavookjian, Jr., M.D., *Stamford*

BUSINESS MEETING

ELECTION OF OFFICERS

IMPORTANT—PLEASE NOTE

The following Sections of the Society will not be meeting on May 8. The programs, dates and times follow:

SECTION ON ORTHOPEDICS
MAY 1, 1986

3:30 P.M. Hunt Memorial Building
230 Scarborough St., Hartford

President: Alan Goodman, M.D., *New Haven*
Secretary: Gerard J. Lawrence, M.D., *Willimantic*

3:30 THE IPA, THE UNION AND YOUR FUTURE
VINCENT LYNCH, M.D., NEW HAVEN; President, New Haven IPA
JOSEPH DINEEN, M.D., ANSONIA; President, Connecticut Physicians Union

5:30 SOCIAL HOUR—FOLLOWED BY DINNER

SECTION ON OTOLARYNGOLOGY
MAY 14, 1986

9:30 A.M. Ramada Inn, North Haven

President: John W. Cavo, M.D., *New Britain*
Secretary: Gordon Strothers, M.D., *New Haven*

9:30 AUDIOLOGIC PATTERNS OF ETIOLOGY SIGNIFICANCE—STRATEGIES FOR DIAGNOSIS
JACK M. SNYDER, Ph.D., University of Washington, Seattle

10:15 VISIT EXHIBITS

11:00 BASIC STUDIES OF DEVELOPING COCHLEAR PROSTHESIS
JOSEF M. MILLER, Ph.D., Professor, University of Michigan; Director of Kresge Institution, Ann Arbor, Michigan

12:00 LUNCHEON

1:00 LASER DOPPLER STUDIES OF THE EFFECTS OF VARIOUS PHARMACOLOGIC AGENTS ON INNER EAR BLOOD FLOW
JOSEF M. MILLER, Ph.D.

1:45 VISIT EXHIBITS

2:15 OFFICE AUDIOLOGY, MACHINES AND TECHNIQUES
JACK M. SNYDER, Ph.D.

SPECIAL NOTICES
CONTINUING MEDICAL EDUCATION CREDITS

AMA PHYSICIAN'S RECOGNITION AWARD

As an organization accredited for continuing medical education by the Affiliation Committee for Continuing Medical Education, Yale University School of Medicine certifies that this program is acceptable for Category 1 credit as specified by the American Medical Association for the Physicians Recognition Award. Credit is granted in this category on an hour for hour basis.

AMERICAN ACADEMY OF FAMILY PHYSICIANS

The Commission on Education of the AAFP has accredited the scientific program of the Society's Annual Meeting for four hours of prescribed credit for the general lectures and one and one half hours of elective credit for each lecture attended which is presented by the individual specialty sections of the Society.

TECHNICAL EXHIBITS

Our exhibits contribute to the value of our assembly by presenting goods and services of interest and importance to physicians. Personal visits to the booth will increase your understanding of the materials and programs on display.

Ayr Insurance Agency, Inc., New Haven, Connecticut
Blue Cross-Blue Shield of Connecticut, North Haven, Connecticut
Connecticut Army National Guard, Hartford, Connecticut
Connecticut Medical Insurance Company (CMIC), Wallingford, Connecticut
Constitution Health Network, Wethersfield, Connecticut
Creative Financial Planning, Hamden, Connecticut
Data Systems of Connecticut, Inc., Milford, Connecticut
Hoechst-Roussel Pharmaceutical, Inc., Somerville, New Jersey
J. P. Lippincott/Harper Row, Philadelphia, Pennsylvania
Physicians Health Service, Trumbull
Professional Systems, Amston, Connecticut
Pro-Med Systems, Inc., New Haven, Connecticut
Real Time Management, Inc., Bridgeport, Connecticut

FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511 Telephone 865-0587

Timothy B. Norbeck, *Executive Director*

Josephine P. Lindquist, *Associate Executive Director*

Raymond T. Sullivan, Jr.
Assistant Executive Director
Public Affairs

Robert J. Brunell
Assistant Executive Director
Scientific Activities

Shelley A. Marcus
Director of
Government Relations

CALL

ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1986 Annual Meeting of the House of Delegates will be held at the Park Plaza Hotel New Haven, commencing at 9:30 A.M. on Wednesday, May 7.

William A. Whalen, Jr., M.D., President
Lawrence B. Ahrens, M.D., Speaker of the House
Norman A. Zlotsky, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides:

Resolutions may be introduced by any Active or Life Member or student members or postgraduate physician members of the Society, in compliance with the following provisions:

a. *All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*

b. *Component county associations or the student members or postgraduate physician members, whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.*

c. *Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.*

d. *Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

Council Meeting

February 6, 1986

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahamed, Ahrens, Beck, Bobruff, Bonner, Canzonetti, Czarsty, Freedman, James, Kaess, Kamens, McDonnell, Petrie, Ragusa, Reyelt, Jr., Robbins, Rose, Sadowski, Scheer, Seide, Villa, Welch, Whalen, Jr., Zanker and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Ms. Marcus, Mr. Sullivan, Mr. Tomat (FCMA), Mr. Meister (NHCMA) and Mr. Fiorentino (HCMA).

Absent were; Drs. Dardick, Friedberg, Orphanos, Schwartz, Sullivan, Jr., Sweet and Waldron.

Reports from Physicians Serving on State and Federal Agencies

Dr. Abbot reported that the main topic at the SHHC meeting was financing, and that it appeared that the government is trying to get out of health planning. HSA's, dependent on government funding, are beginning to wind down and will probably be out of business by October, unless they are able to obtain funds from private sources or from state legislature. They will need $125,000 each to stay in operation. HSA IV is funded by insurance companies and CBIA. SHHC is an item in the Governor's budget and, therefore, it is more secure. Dr. Abbot also reported that the MRI Task Force is going into phase II and has received permission to enlarge the Task Force. The staff report on CSMS monitoring of legislation and regulatory agencies was received as information.

Report of the President

Dr. William Whalen reported on the following:

IPA/HMO: The ad hoc committee is moving along very rapidly. Several consultants appeared before the committee and on January 13, Mr. Tom Garvey was selected to do all the preliminary work to determine the feasibility and advisability of proceeding with an IPA/HMO on a statewide basis and also to draw up a business plan. Mr. Garvey informed the committee that he will have a complete report by April 15 which will be in time for distribution to the House of Delegates meeting. If "all systems are go," it is conceivable that by December 1, 1986, CSMS could have a program in action.

Social Admissions: This problem is still unresolved and based on Dr. Whalen's comments, it was VOTED to support a study of social admissions in the health services for the poor and elderly in Connecticut and refer the subject to the Committee on Statewide Medical Planning for implementation. Data on this subject is available from the CPRO experience. The AMA delegation should be prepared to introduce a resolution at the AMA June 1986 meeting based on any recommendation that is forthcoming from the study.

Update on Nursing Home Visits

Dr. Joseph Czarsty reported that a position paper has been drawn up and sent to the members of the congressional delegation that are assisting the committee and that a meeting is being set up for CSMS representatives with HCFA in Boston. Overtures have been made to the Medicare carrier expressing our willingness to reinstate our Liaison Committee providing the committee would have some input in developing regulations. CSMS staff has already arranged a meeting with the Medicare carriers to pursue this matter. Information on this subject has also been sent to the AMA for action.

Report of the Executive Director

Mr. Norbeck reported on the Medical Malpractice Forum which was arranged by the New London County Medical Association. It was held in the New London High School and representatives of CSMS, CMIC and attorneys participated in the forum. There were quite a few attorneys in the audience and it was felt that their questions were fully answered.

He further reported that some positive public relations had been generated for physicians, as a result of the defensive medicine survey, until an article appeared in the *New York Times* quoting Arnold Relman, M.D., Editor of the *New England Journal of Medicine*, concerning statistics regarding incompetent physicians. Immediately the media picked up on Dr. Relman's statements, whose statistics were incorrect, and published articles on the issue. A telephone call was directed to Dr. Relman asking him if he made these statements, where, and in what context, and did he mind sharing his documentation with us. It was also VOTED to authorize the Chairman of the Council to direct a letter with a copy of the editorial to Barbara Rockett, M.D., (President of the Massachusetts Medical Society) expressing concern about Dr. Relman's comments, as reported in the press, and also requests documentation of the statistics used.

The First Aid For Sports Injuries Coaches Module, which was prepared by the Greater Hartford Chapter of the American Red Cross in cooperation with CSMS, which had been distributed to Council members, was brought to their attention. Dr. Zlotsky, who has been active in the Committee on Medical Aspects of Sports reported that this is one of the first modules to be published and that it will be receiving national recognition.

Resolutions Re Election of CMMI Directors and CMMI Bylaw Changes

A set of resolutions had been distributed to the Council which were proposed by Dr. Raymond James relating to the election of CMMI Directors and CMMI Bylaw changes. Following lengthy discussion the following resolutions were approved.

RESOLVED, That the Council of the Connecticut State Medical Society shall nominate and select directors for election by the House of Delegates of the Connecticut State Medical Society at the CMMI annual meeting.

RESOLVED, That Society approval of CMMI bylaw changes shall require two-thirds majority of delegates present and voting in a duly called meeting of the House of Delegates. The call of the meeting shall include copies of the proposed bylaw changes.

RESOLVED, That the President of CSMS be authorized to act as a shareholder on behalf of CSMS at the annual meeting of CMMI.

RESOLVED, That Section 2.01 of Article II of the Bylaws of Connecticut Medical Management, Inc. be revised to read as follows:

> Section 2.01 Annual Meetings: The annual meeting of shareholders, for the election of Directors and for the transaction of any other business relating to the affairs of the Corporation which may come before the meeting, shall be held annually on such date, within the first six months of each year, as the Board of Directors shall designate.

Dr. James and Dr. Freedman discussed other items that appeared in the proposals submitted, such as terms for directors, committee functions, etc. It was VOTED to accept these comments as information.

It was VOTED to table further discussion on the proposals submitted by Dr. James.

Committee on Drug Abuse

It was VOTED to approve the request of the Committee on Drug Abuse Education to change the name of the committee to the Committee on Physician Health. Among the reasons given for the change is the committee's long-standing and probably permanent concentration on issues relating to the discovery and treatment of impaired and potentially impaired physicians. Also, the committee's involvement extends beyond drug abuse to other forms of addiction and other types of chronic and degenerative illnesses.

Nominations for CMIC Board

Nominees for CSMS Council approval were submitted by the CMIC Board of Directors, in accordance with the CMIC Bylaws. It was VOTED to approve the following nominees: Kenneth R. Kaess, M.D., Winsted; Stanley J. Keating, Jr., M.D., Simsbury; Clayton B. Weed, Jr., M.D., Stamford; Guy W. Van Syckle, M.D., Danbury; Stewart J. Petrie, M.D., Derby and Michael R. Sharon, M.D., Rockville.

Extension of Medicare Freeze

Dr. Van Syckle reported that he had been asked by colleagues to bring this subject to the attention of the Council for discussion. The freeze has been extended to March 15 for both participating and non-participating physicians. He reported that not only the medicare allowance was frozen but the right to balance bill was also frozen. He reported that it appears that this freeze will be extended for a year. Based on this, it appeared that there are two methods of relief, judicial and legislative. In talking to the AMA legal department, he was informed that the AMA was not going to pursue the constitutionality of the freeze. Correspondence has been sent to the appropriate heads of the AMA departments dealing with this issue requesting that some information be issued as to why this matter is not being pursued. CSMS legal counsel reported that they had reviewed the action of the AMA not to pursue the issue and also the action taken in Georgia and in their judgment that it was a losing proposition and reported some of the reasons on which the decision was made. One of the prime reasons for not pursuing is that it is entirely voluntary on the physician's part to participate in the program. Physicians are not required to take Medicare patients. Following lengthy discussion, it was VOTED that legal counsel prepare a summary of what was reported, which can be published in *Connecticut Medicine,* including in the summary what has been done, what could be done and what pitfalls there are in the law which could affect physicians. It was further VOTED that staff and the AMA delegation keep this issue in the forefront at state and national level.

Report on Meeting of Ad Hoc Committee on CSMS Annual Meeting

Members of the Council had received copies of the report of the meeting of the Ad Hoc Committee with their agendas. There were two parts to the report. The first ten items in the report were unanimously agreed upon by the committee and Dr. Van Syckle Chairman of the Ad Hoc Committee reviewed each of the items. Following discussion it was VOTED to approve the ten recommendations as follows:

1. Hartford and New Haven are the best locations with parking facilities to be given a high priority;
2. to establish a repetitive week in spring and fall for semi-annual and annual meetings, i.e., last week of April, first week of November;
3. make dates several years in advance which would allow scheduling speakers and other activities with more facility;
4. meeting to be started in the morning at 9:30 -10:00 with lunch break followed by afternoon session with target conclusion by 4:00 P.M.;
5. have reference committees meet as early business and their reports be the last items of business;
6. actively publicize the date of the meeting in multiple publications beginning three months before the meeting;
7. obtain a top speaker to address the delegates at lunch;
8. improve audio-visual equipment;
9. meeting of the reference committee chairman and members together with the speakers to familiarize them with procedures and duties prior to the actual meeting;
10. recommendations of the reference committee to be printed and distributed to the House of Delegates prior to the verbal report of the reference committee.

It was further VOTED to supplement the educational aspect of the House of Delegates meetings with panel discussions of pertinent topics, i.e., physician DRG's, physician unions, etc.

It was also VOTED that the Council appoint an ad hoc committee to suggest certain issues of vital interest to medicine and that these be sent to the counties for discussion to generate issues and resolutions for the House of Delegates.

AIDS and Directed Donations

The CSMS Committee on Organ and Tissue Transfer submitted a report to the Council stating that because of current public concern regarding the safety of our blood supplies, the Connecticut State Medical Society's Committee on Organ and Tissue Transfer has reviewed its 1983 statement on "AIDS and Directed Donation" which was accepted in principle by the CSMS Council on July 6, 1983. Following a review of current policies regarding testing of blood donations and the fact that no data has come to the attention of the Committee to suggest that directed donations increase its safety, the Committee requested the Council to also reaffirm its acceptance of the recommendation that Connecticut hospitals and the Connecticut Red Cross blood services not offer directed donations. Following discussion, the Council VOTED to support this recommendation.

Report from Committee on Statewide Medical Planning

Medicare Freeze—Preadmission Certification

Several items had been submitted to the Committee on Statewide Medical Planning for study and report. The following is action taken on the committee's recommendations:

a. CSMS action in support of physician members charged for alleged violations under the fee freeze.
   1. It was VOTED to retain CSMS Counsel to list and explain a physician's legal burdens and potential pitfalls, and publish this information to the membership after Council approval.

      It was VOTED to offer an opportunity to CSMS members accused of an alleged violation the opportunity to appear before the Committee on Third Party Payments, which then could make appropriate recommendations to the Council or the member.

      It was VOTED to reaffirm the Society's position opposing the extension of the fee freeze.

b. CSMS position about the added work by physicians' staffs to satisfy governmental and third party payor regulations related to preadmission certification.
   1. It was VOTED that the Council communicate to the AMA the CSMS's support of the AMA study of third party payor paperwork costs, and that CSMS looks forward to the AMA Board of Trustee's report on this subject at the annual meeting in June.

      It was VOTED that CSMS supports the concept of fair compensation to physicians for excess time and staffwork in meeting third party payor requirements.

The Committee reported that a thorough report had been received from Dr. Edward Kamens, Medical Director of CPRO, who stated that after initial telephone equipment problems, the paperless preauthorization process is working more swiftly, retroactive denials have been sharply reduced, and hospitals are regaining lost waivers, while others are out of danger of losing them. He also stressed that emergency situations do not require precertification, but only certification within two working days.

Following discussion, the Council VOTED to approve the recommendation of the committee that CSMS reaffirm its commitment and support for CPRO as its own physician-directed statewide peer review organization.

Update on AMA Health Policy Agenda

Dr. Abbot, CSMS representative on this committee, reported that the study is in its third and final year and that the advisory committee will probably meet one more time in May. It is expected that the final report will be available by the end of 1986 and then will be taken over by a task force on implementation. The AMA Journal had a report on the HPA in January 1986 and *JAMA* will probably have another article in the June issue. It was VOTED to receive Dr. Abbot's report as information.

Committee on Third Party Payments

It was VOTED to accept the resignation of Dr. S. P. Browning, III, Norwich, from the subject committee with thanks and appreciation for his long and valued service to the affairs of the Society.

Hospital-Based Physicians

It was VOTED that the bill being introduced by Gardner Wright, M.D., concerning radiologists and anesthesiologists be referred to the Committee on Legislation for action, noting that the Council is opposed to additional government regulations.

Committee on Hospitals

The Council had referred several items to the Committee on Hospitals for study and report. Following is the action taken on the committee's recommendation:

1. *Contract Evaluation Unit:*

   It was VOTED that CSMS should retain appropriate legal counsel to develop guidelines and caveats for physicians considering group contracts, for promulgation by CSMS to the membership.

   It was VOTED that CSMS should receive and solicit copies of such proposed agreements for analysis and evaluation by said legal counsel for the benefit of affected member physicians, as was done with the BC-BS Century 2000 PPO program last fall.

2. *Legal Review of Hospital Medical Staff Bylaws:*

   It was VOTED to table a recommendation that CSMS retain appropriate legal counsel to develop model medical staff bylaws and other guidelines, to aid medical staffs. Appropriate materials are available from the AMA.

3. *Hospital Medical Staff Section (HMSS)*

   Previous efforts to organize a CSMS Hospital Medical Staff Section to relate to the AMA HMSS have not been effective. It was VOTED to approve of the Committee on Hospital's proposal to have an invitational meeting for all hospital staff presidents and chiefs, previous hospital delegates to the AMA HMSS, and the CSMS delegation and officers, for the purpose of inaugurating a CSMS HMSS, as previously authorized by the Council.

Committee on Public Health Report Re AIDS

It was VOTED to endorse the following resolutions, which were submitted by the CSMS Committee on Public Health:

Whereas, the condition known as Acquired Immune Deficiency Syndrome is of deep and continuing concern to Connecticut residents, the Committee on Public Health has approved the following for endorsement by CSMS:

1. The policy statements of the Centers for Disease Control as printed in the Morbidity and Mortality Weekly Reports of November 15, 1985 and December 6, 1985.

   November 15, 1985 - "Summary:"

   "Recommendations for Preventing Transmission of Infection with Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus in the Workplace."

   December 6, 1985

   "Recommendations for Assisting in the Prevention of Perinatal Transmission of Human T-Lymphotrophic Virus Type III/Lymphadenopathy-Associated Virus and Acquired Immunodeficiency Syndrome."
2. That Connecticut communities, with the cooperation of the State Department of Health Services and local official and voluntary health agencies and hospitals, plan and provide for post-hospital care for AIDS patients.
3. That there be no mass pre-employment or pre-marital screening for AIDS.
4. That alternate testing sites for AIDS be provided for those at high risk and that anonymity be maintained at these sites.
5. That AIDS in children does not constitute a threat to any school children, teachers, administrators or other school employees.
6. That anonymity be maintained for children with AIDS.
7. That CSMS appoint a task force of knowledgeable physicians concerned with AIDS.

It was further VOTED that the Committee on Public Health should act as the task force, as recommended in item 7 of the above resolution.

Report on *CONNECTICUT MEDICINE*

Dr. Stewart Petrie, Editor Pro tem, reported that *Connecticut Medicine* is under control and that he had an interesting and very good Editorial meeting which was well attended and that the next few issues of *Connecticut Medicine* are in good order due to staff and preliminary work of Dr. Fabro. Dr. Robert Massey has been appointed Chairman of the Search Committee for a new editor and it has been widely publicized that the position is open. A resolution and several suggestions which were made by the Editorial Committee were discussed and the following action taken:

It was VOTED to approve the following statement:

"In recognition of his accomplishments, his devotion to high standards and his skill as an editor, we the Editorial Committee of *Connecticut Medicine* and the Council of CSMS hereby commend, thank and praise Dr. Fred Fabro. Under his nurturing care, the *Journal* has not only thrived, but vastly improved; he leaves behind a much finer product than he found when assuming his duties in November, 1972. We are grateful to have served under his direction, and wish him good health and productivity in his well-deserved retirement."

It was VOTED that Dr. Fabro be designated Editor Emeritus and that his name appear on the Journal masthead, pending his approval and acceptance of such designation. It also was VOTED that the resolution and a suitable plaque be presented to him at the House of Delegates meeting.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on February 6, 1986. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

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The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

DERMATOLOGY

The Northeast Permanente Medical Group, P.C., the Medical Group for the Hartford Connecticut area of the Kaiser Permanente Medical Care Program's Northeast Region, is seeking a board certified or eligible dermatologist in 1986. The Hartford area currently serves over 23,000 members from two ambulatory care facilities in East Hartford and Farmington. The Medical Group is a multispecialty prepaid practice organized as a professional corporation. Applicants should be willing and qualified to provide ambulatory primary care while establishing a full-time dermatology practice. Salary and benefits are highly competitive. All inquiries and resumes should be addressed to: Daniel A. Gregorie, M.D., Regional Medical Director, Northeast Permanente Medical Group, P.C., 60 Washington Street, Suite 401, Hartford, CT 06106.

Active Dermatology Practice for sale in central Connecticut. Doctor retiring; will introduce. Write CSMS, c/o DERM/JJ.

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Northeastern Connecticut. Group of two Family Practitioners seeking third to replace a departing Family Physician. Must do obstetrics; excellent financial package; mid-sized community hospital; full privileges available. Reasonable distance from Providence. Contact Diane Fegatelli (716) 884-3700 or write 4-CS Vermont St., Buffalo, NY 14213.

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INTERNAL MEDICINE

Internist needed for Locum Tenens starting approximately April 1, 1986 at the Community Health Care Plan, Bridgeport, CT, for a period of 2 to 3 months. Hospital privileges in Bridgeport desirable. Excellent temporary opportunity. For details, contact: Ron Blumenfeld, M.D., Medical Director, Community Health Care Plan, 4000 Park Avenue, Bridgeport, CT 06604. (203) 371-1582.

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B/C or B/E internist sought by three physician primary care group in New Haven, Connecticut. Office well-equipped with laboratory and x-ray facilities. Initial salary with goal toward partnership. Send resume to CSMS, c/o IM/FF.

Seeking BC/BE internist to rapidly become partner in 3-½ year old general internal medicine practice. Modern, computerized office on shoreline. Office located just six minutes from Yale-New Haven Hospital. Candidate must be willing and enjoy working with elderly as there is a heavy emphasis on quality geriatric medicine and nursing home care, besides a general medicine population. If interested, please send CV to CSMS, c/o IM/PP.

The Northeast Permanente Medical Group, P.C., the Medical Group for the Hartford, Connecticut Area of the Kaiser Permanente Medical Care Program's Northeast Region is seeking board certified or eligible internists for 1986. The Hartford area currently serves over 23,000 members from ambulatory care facilities in East Hartford and Farmington. The Medical Group is a multi-specialty prepaid practice organized as a professional corporation. Applicants should have a strong interest in primary care. For qualified candidates, there is substantial opportunity for a combined subspecialty practice. A rheumatology subspecialty is particularly desirable. Salary and benefits are highly competitive. All inquiries and resumes should be addressed to: Daniel A. Gregorie, M.D., Regional Medical Director, Northeast Permanente Medical Group, P.C., 60 Washington Street, Suite 401, Hartford, CT 06106.

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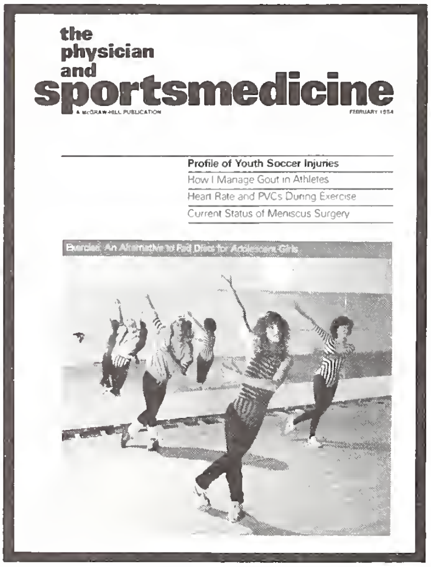

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PHYSICIANS WISHING TO PRACTICE IN THE STATE OF CONNECTICUT

INTERNAL MEDICINE

July '86. Age 30. Nat'l bds. AB cert. MD, S.U.N.Y., Downstate Medical Center, Brooklyn, NY: Int. and Res., Kings County, Downstate, (Brooklyn VA Hospital); Fellowship, Nassau County Medical Center (Gastro), NY. Seeking position as associate/partner in small group. Fully trained in all routing endoscopic procedures. Write, Frank J. Karpowicz, M.D., 200 Carman Ave., Apt. 8C, East Meadow, NY 11554.

July '86. Age 34. AB elig. MD, Guntur Medical College, India; Int., Government General Hospital, India; Res., V.A. Medical Center, Wilkes-Barre, PA. Prefers solo, group or associate type practice in a medium-sized community. Write, R.R. Makkena, M.D., 501 Indian Creek Dr., Wilkes-Barre, PA 18702.

July '86. Age 27. FLEX. AB elig. MD, Universidad Central del Este, Dominican Republic; Int. and Res., St. Joseph's Hospital, Paterson, NJ. Desires solo or associate type practice. Write, Roger Steinfeld, M.D., 100 Hospital Plaza, Apt. 807, Paterson, NJ 07503.

July '86. Age 31. Presently in practice. Nat'l bds. AB elig. MD, New York Medical College; Int. and Res., Montefiore Medical Center. Prefers group or associate type practice. Write, Joseph Cohen, M.D., 16 Mountainbrow Townhouse, Corning, NY 14830.

CARDIOLOGY. July '86. Age 31. Nat'l bds. AB cert. (IM), AB elig. (Card.). MD, University of Virginia; Int. and Res., Albany Medical Center, Albany, NY; Fellowship, Cleveland Clinic Foundation, Cleveland, OH. Prefers solo, group or associate type practice with invasive and noninvasive cardiology. Write, Brian L. Kaminsky, M.D., 2617 Shaker Rd., Cleveland Heights, OH 44118.

GASTROENTEROLOGY. July '86. Age 32. FLEX. AB elig. MD, St. George's University School of Medicine, Grenada, West Indies; Int. and Res., The Greater Baltimore Medical Center, Baltimore, MD; Fellowship, St. Mary's Hospital, Rochester, NY. Prefers group or associate type practice. Write Robert L. Yin, M.D., 19 Pinnacle Rd., Rochester, NY 14620.

GASTROENTEROLOGY. July '86. Age 30. Nat'l bds. AB cert. MD, Downstate Medical Center, NY; Int. and Res., Johns Hopkins Hospital, Baltimore, MD; Fellowship, New York University Hospital, NY. Prefers group or associate type practice in a large-sized community. Write, Brian C. Weiner, M.D., 24 Bowling Green Place, Staten Island, NY 10314.

PULMONARY. July '86. Age 36. Licensed in Connecticut. Nat'l bds. AB elig. MD, Universidad Central del Este, Republica Dominicana; Int. and Res., Perth Amboy Hospital and the New Jersey College of Medicine and Dentistry; Fellowship, Norwalk Hospital and Yale University School of Medicine (Pulmonary). Prefers solo, group or associate type practice in a medium-sized community. Write, Fred Wagshul, M.D., 55 Mill Plain Rd., Unit 16-4, Danbury, CT 06811.

PATHOLOGY

Feb. '86. Age 38. Nat'l bds. AB elig. MD, New York Medical College, Valhalla, NY; Int., Yale-New Haven Hospital, New Haven, CT; Res., University of California, Sacramento, CA. Prefers associate type practice. Write, Leslie Dowd, M.D., P.O. Box 546, Manchester, CT 06040.

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AMI

The Cochlear Implant: An Overview

LORI WILLS, M.S., C.C.C.-A., K. J. LEE, M.D. AND EIJI YANAGISAWA, M.D.

Introduction

The Cochlear Implant holds great promise in improving the communication ability of the profoundly deaf. It has been endorsed enthusiastically by the American Medical Association and is a revolutionary development in ear surgery of the Twentieth Century.[1] There are as many as 200,000 to 250,000 profoundly hearing impaired in the United States who may prove to be candidates for an implant.[2,3] The implant replaces the function of damaged cochlear hair cells by direct electrical stimulation of the VIII Nerve neurons in the cochlea. Implanted, a patient experiences greatly improved environmental awareness and increased speechreading abilities. Highly successful patients report speech understanding with and without visual cues.

History

Experimental work involving the implantation of electrodes directly into the auditory nerve began in the U.S. in the 1960's. With the development of microsurgery techniques in the 1950's and electronic miniaturization in the 1960's, the possibility of implant surgery became feasable. Knowledge of sophisticated insulating materials and prosthesis biocompatibility, acquired through pioneer work with pacemakers, helped lay the groundwork for today's cochlear devices.[4,5]

Investigators knew the cochlea functioned as a transducer of acoustic to electrical energy. This concept was applied to the theory that electrically stimulating the auditory nerve directly would produce artificial hearing. In 1961 House implanted a single wire electrode into the scala tympani of a patient. By 1966 Simmons was implanting electrodes in the VIII Nerve through the modiolus.[5,6] In 1971 Michelson described a multichannel scala tympani system he had implanted.[4] Throughout the 1970's investigators such as Eddington, Clark, and Hochmair published their data on newly designed Cochlear Implant systems.[5] Now in the 1980's there are a number of Cochlear Implant teams advocating their devices.

Description of Cochlear Implant Devices

Cochlear Implant design is in a constant stage of flux. Today's device will be upgraded tomorrow. Basic components in all devices include an implanted electrode or electrodes, a microphone, and a microelectronic processor that transduces sound to an electrical signal.

All devices are stimulating the auditory nerve directly but, differ in number, placement, and grounding methods of electrodes, and in pattern of speech processing. The connection between the internal and external components can be made by direct wire contact penetrating through the skin (percutaneous) or it can be made through electromagnetic induction across an intact skin (transcutaneous).[7,8]

Speech processors are battery operated and approximately the size of a cigarette box. They include patient control dials for volume and limited compression and frequency control. Some devices have accessories that are compatible with the telephone.

Differences

Electrodes among the different devices range in number from one to 22. They are placed in the scala tympani (intracochlear) or at the round window (extracochlear) and located at or near speech frequency sites of the cochlea.[8] Grounding methods differ depending on the type of electrode array. Bipolar electrodes pass current between two locations and restrict the current to a more limited portion of the cochlea. Bipolar electrodes better control stimulations, allowing for a wider dynamic range and more discrete stimulation. A remote ground electrode creates a greater distribution of current. Several electrodes are linked together to create a common ground in some devices.[9,10]

LORI WILLS, M.S., C.C.C.-A., Project Coordinator, Cochlear Implant Center of Southern New England; Staff Audiologist, Hearing Aid Center of Southern New England. K. J. LEE, M.D., Chief of Otolaryngology, The Hospital of St. Raphael; Director, Ear Research and Educational Center and Otolaryngologist, the New Haven Ear, Nose, Throat and Cosmetic Facial Plastic Surgery Center. EIJI YANAGISAWA, M.D., Associate Chief of Otolaryngology, The Hospital of St. Raphael; Otolaryngologist, the New Haven Ear, Nose, Throat and Cosmetic Facial Plastic Surgery Center, New Haven, CT.

Reprint requests to: 98 York St., New Haven, CT 06511 (Dr. Lee).

Connecting the internal and external portions of the device can be done percutaneously. This permits more direct contact but increases the chances of infection. Transcutaneous connections are possible through electromagnetic induction or a radiofrequency carrier wave.[7,10]

Single or multichannel, analog coding or systems that extract salient speech features change the way speech is reproduced.[7]

Significance of Differences

Only through trial and error will investigators conclude which electrode array and speech coding strategy is superior. Much of the evidence is, as yet, inconclusive. Definite information is emerging, however, which shows superior patient performance with multichannel systems. Better speech understanding is occurring and attributed to improved frequency resolution of multichannel devices.[3,7,11] The single wire electrode excites such a large group of neural fibers that different pitches cannot be distinguished. Speech cannot be understood without visual cues in a single channel system. Multielectrode devices make pitch perception possible. Some spread of current still occurs but more distinct groups of auditory fibers are stimulated and improved speech results have been noted.[3,7,11]

Auditory fibers in the normal functioning cochlea have a 20-40 dB dynamic range. Electrical stimuli demonstrate a dynamic range of only 4 dB. The Cochlear Implant must be provided with a stimulator that can compress the intensity range to adapt to the limitations of electrical stimuli, while processing important parameters of speech that are necessary for speech recognition.

The best method of coding speech is unknown. Analog strategies, feature extraction methods, or a sinusoidal carrier signal are currently used in speech processors.

Analog systems provide a direct electrical reproduction of the speech signal that has been amplified, bandpass filtered, and compressed. The frequencies from a speech signal are divided into bandwidths and presented to corresponding areas of the cochlea.

Feature Extraction strategies utilize pulsatile stimuli varying in rate, width, and amplitude. Speech features are extracted corresponding to rate of stimulation, place of stimulation or electrode chosen; and is determined by such cues as fundamental frequency and second format information.[12,13,9,5,3]

Bandpass Filtering and Feature Extraction are using the frequency organization of the cochlea. Stimulation of basal electrodes are perceived as high pitches and apical electrodes as low pitches. While these strategies have been proven effective, further advances in Speech Science and Bioengineering are needed in order to discover the best speech coding technique.[12,13,9,5,3]

Devices Prevalent in the U.S.

FDA approval of the House/3M singlechannel device for widespread use in postlingually deafened adults was granted on November 29, 1984.[2] Nucleus of Cochlear Corporation received FDA approval on November 11, 1985. There are nine major Implant projects worldwide. Three U.S. Cochlear Implant teams are presently undergoing investigation by the FDA and involved in clinical trials. These investigators include: Storz of St. Louis in conjunction with the University of California at San Francisco; Symbion, Inc. of Salt Lake City with the University of Utah; and Biostim, Inc. in Princeton, New Jersey.[13,10]

The House/3M Device

The House/3M Cochlear Implant is a singlechannel, Intracochlear device. It has been the most widely used implant to date and one of two devices fully approved by the FDA. The Nucleus device received approval in November 1985. The active electrode of the House/3M device is inserted 6mm into the scala tympani and the Implant receiver is implanted under the skin near the pinna. A microphone rests over the patient's pinna and connects by wire to a speech processor that amplifies and codes the signal. The signal is bandpassed and a modulated signal travels to the external coil transmitter that communicates through magnetic signals to the internal coil. The internal coil carries the message to the active electrode. The electrode may be less likely to damage cochlear tissue as it is not implanted as deeply as most other devices.[7,11]

The Storz/UCSF Device

The internal Storz device consists of an Intracochlear electrode, a connector and a multichannel implantable receiver with 4 channels that are being upgraded to 8 channels in the near future. Four antenna coils are implanted under the skin that communicate with the external portion. The external portion includes an external array of antenna coils, worn above the ear and held in place by magnets. It also includes a speech processor with microphone, preamplifier, analog processing, bandpass filters and linear compressors. These latter items connect by thin cables to the external array.

The Storz/UCSF electrode has a predetermined electrical shape that allows for safer insertion and permits further insertion in order to reach the speech frequency region of the cochlea (22-25mm).

The connector system permits accessibility so that the device can be upgraded through a simple surgical procedure.

Bipolar stimulation of 8 electrode pairs occurs simultaneously through all channels.[10,7,11]

The Nucleus Device

Formal FDA approval of this device was granted in November, 1985. A twenty-two electrode array is inserted approximately 25mm into the cochlea and the implanted receiver/stimulator receives information from the externally worn microphone headset. The headset has a directional microphone and transmitter coil and is placed over the internal site.

Sound is coded by the wearable speech processor and sent to the receiver/stimulator which generates biphasic stimulus current pulses to preselected electrode pairs. Stimulation occurs sequentially.[9,10]

Electrode programming occurs through the use of a computer, the Diagnostic and Programming Unit. An electrode can be made active or inactive and grounding schemes are changeable depending upon the user's responses. Thresholds and Maximum Comfort Levels to electrode stimulation can be stored and modified through the computer programming.

A Feature Extraction system codes the speech signal. Features of speech are processed that are theoretically believed to supply the necessary information for speech understanding, such as amplitude and speech format information.[9,13]

The Symbion/University of Utah Device

Marketed as Ineraid, the Symbion Device is also multichannel. An implanted electrode assembly consists of 8 electrodes inserted into the scala tympani, 4mm apart. It is believed this careful spacing of the electrodes enhances pitch perception. Two electrodes serve as remote ground. Four electrodes communicate with the 4 channel sound processor through a carbon percutaneous connector and an earhook assembly.

The channels work simultaneously and sound is transformed into an electrical analog and processed through a bandpass filter system corresponding to apically through basally placed electrodes.[10,7]

The Biostim, Inc. Device

Named Bioear, the Biostim Implant is a single channel device with an Intracochlear electrode placed 3mm into the round window. The microphone of the speech processor picks up sound and it is transmitted transcutaneously to an implanted receiver/stimulator.

Three coding strategies are available in one speech processor so that analog and pulsatile waveforms can be generated with the device.

The Team Approach

Design, development, manufacturing, and actual use of and adaptation to the Cochlear Implant occur through a multidisciplinary approach involving medical companies, hospitals and clinics, Physiologists, Otologists, Audiologists, Speech Scientists, Engineers, Psychologists and other professionals.

Medical management and the ultimate decision of whether to implant a patient is the role of the Otologist but, the Audiologist and Psychologist provide candidacy information through diagnostic testing and counseling, acquiring liaison roles between patient and physician.[11,14] The morbidity of cochlear implant surgery is not dissimilar to that of routine mastoidectomy-tympanoplasty and canalplasty. The patient is discharged on the first or second post-operative day.

Patient Selection

Candidacy

Although children and the prelingually deafened are being implanted with Cochlear Implants on a very controlled basis at certain centers, most Implant projects are applicable to healthy, postlingually deafened adults who find no benefit through the use of hearing aids or tactile devices. They must be at least 18 years old with profound bilateral sensorineural deafness and patent cochleas.

Candidacy considerations include degree of family support, geographical distance from and accessibility to the Implant Center, and the patient's overall personality and motivation. Financial and insurance status of the patient is another important consideration. The device itself, hospital and surgical fees, and rehabilitation costs can total between $14,000-$20,000.[10,11] Success with the implant varies greatly and has been attributed to the above factors as well as the patient's age, their expectations and social and vocational history, their family's attitude, the etiology of deafness, number of years of deafness, their preoperative receptive and expressive language competence, neural population reserve, their cognitive processing skills, and ability to synthesize speech information.[14,9,12,15,13,16]

Patient Evaluation

Following the otological and vestibular examination, an ENG and a CT scan or Polytomography are scheduled.

Complete Audiometry testing is administered during the initial stages of patient selection. Pure tone air conduction and bone conduction testing, Tympanometry results, including Acoustic Reflex Testing, are obtained, if possible. Speech Reception Thresholds (or Speech Detection Thresholds) and Speech Discrimination scores are attempted. Preferably, recorded speech materials are used. ABR testing is often completed as well.

A Hearing Aid Evaluation is performed and, if the patient is not currently wearing amplification, a trial period with appropriate hearing aids or tactile device is recommended.

Recording speechreading tests and tests assessing listening capabilities of the profoundly hearing impaired are administered aided and unaided. The MAC Battery[17] and CID sentences are the most commonly used. This initial audiometry testing provides the baseline for postoperative comparisons.

A visual screening test measures far distance acuity, essential for speechreading.

A Psychological Evaluation provides information regarding the patient's mental status and preimplant expectations. Psychological support is often recommended postoperatively as well.

Questionnaires that assess the patient's perceptions of his handicap and Implant expectations questionnaires are often given. The patient should have a clear understanding of the Implant and the way it functions and agree to the time committment involved in rehabilitation. A model implant and speech processor should be made available. Information booklets describe the device in detail and the patient is required to read them. Counselling is stressed before and after surgery.

The Promontory test, electrical stimulation of the promontory by a needle electrode, is another requirement for many Cochlear Implant Projects. It appears indicative of identifying intact and excitable nerve fibers.[18] Poor responses during the Promontory test contraindicate surgery for some Implant projects.

Results

Implant Design and electronics, degree and quality of rehabilitation, and patient variability may play a role in successful implant use.

Single channel devices are limited to sound awareness.[19] Although they provide auditory cues that facilitate speechreading ability, speech perception without visual cues is not possible. Single channel users become aware of their environment, hearing alarms, running water, footsteps, the telephone and traffic. They turn around when spoken to and use a code on the telephone. Improved speech production occurs as the patient can now monitor their own voice and regain a more natural voice quality. They feel more socially involved and no longer interrupt conversations. They report feeling more independence and experience less emotional stress. Single channel users describe what they "hear" as buzzes, whistles, chirps, and metallic sound.

Multichannel devices provide all of the above. Some multichannel users also experience speech reception. Voices are perceived as voices, but gravelly or shrill. Claims of 40% to as high as 80% speech discrimination without visual cues are reported with the use of multichannel devices.

Rehabilitation

Successful implant use improves with time. Speech understanding with multichannel devices takes listening experience and may require as long as 1-2 years.[13] Rehabilitation to sound begins two to eight weeks postoperatively when the Audiologist custom fits the speech processor to the newly implanted patient. Tests and practice drills are used in helping the patient improve speechreading skills. Environmental sounds, open and closed-set vowels and consonant recognition tasks, words, phrases, and sentences are presented with and without visual cues as the patient relearns hearing.

The speech processor is adjusted as the patient adapts to incoming sounds. Dynamic ranges, from audibility to uncomfortably loud levels, usually widen.[9,7]

Comparing Results

Standardization of rehabilitation test protocol is lacking. Each project uses different measures. Some may tailor tests to their particular Implant.[13] Very little objective comparisons have been performed. Implant groups may be purposely resisting standardization. They may fear the competition, as variables facilitating success are largely unproven.

Recent work at the Iowa Clinic, an objective site, involves a longitudinal study of different implant designs.[13] Results are showing substantial improvement in sound awareness and speechreading ability. Large differences in performance exist between patients, but there are too many factors involved to attribute this to the device design alone.

Research Needs

The role of auditory nerve survival and its relationship to psychophysical parameters is still unknown.[12,16] As knowledge increases, diagnostic tests are needed to determine degree and pattern of nerve intactness. Knowing the nature of nerve survival may help implant teams chose a type of implant that best suits the patient.[12,13] In a patient with poor nerve survival, a multichannel Cochlear Implant may not have any significant advantage over a single channel device.[14] Psychophysical characteristics are in need of further study to promote speech processing strategies and Implant design.[12]

Advances in mechanical and cosmetic design of external device components is also needed. Speech processors and their cords, cables, headsets, magnets, etc. are wearable, but cumbersome for everyday use and often lack durability.

Target Population of the Future

Early intervention is the key to language development in the hearing impaired child. For this reason, children are being implanted cautiously on a controlled, experimental basis. Overexpectations of parents, unkown long range physiological damage from a prosthetic device, and effective teaching methods have been concerns.

Prelingually deaf adults are also being implanted in an experimental basis. The prelingually deaf who have been implanted take longer to adjust to sound. They experience sound as a feeling or vibration in their head. With time, changes in their voice quality is noted. They enjoy music and environmental sounds. Most report feeling more independent and less lonely.[20]

Conclusion

Cochlear Implants are far from replacing normal hearing but, offer sound awareness and possible speech recognition to individuals living in silence. Implants provide hope for a population that, previously, had no medical or surgical options. The deaf are now given the opportunity to become active participants in the hearing world. At the Cochlear Implant Center of Southern New England, thirteen multichannel devices have been implanted within the past eight months. We look forward to reporting on our results next year.

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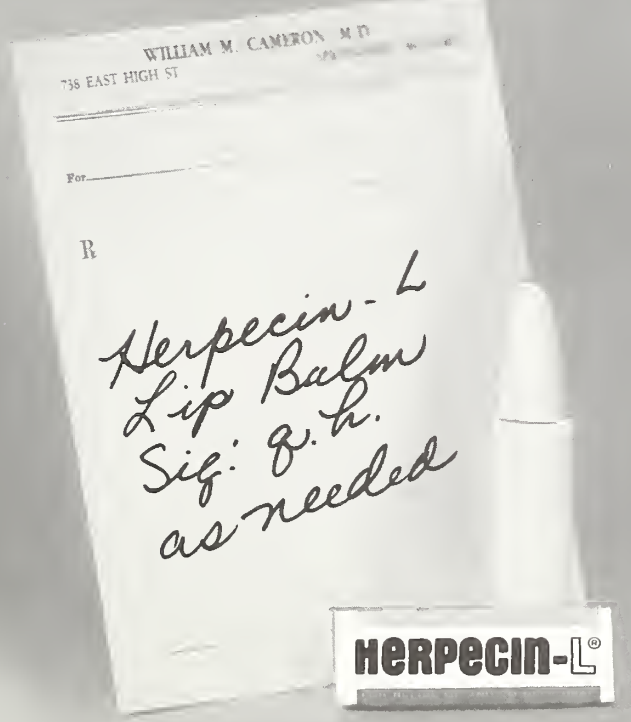

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BEHIND THE FACE OF HYPERTENSION

Massive Rectal Bleeding in Crohn's Colitis

OVLETO CICCARELLI, M.D. AND GEOFFREY M. COLEY, M.D.

ABSTRACT— An 84-year-old female suffered a life-threatening lower gastrointestinal hemorrhage. At emergency laparotomy a thickened inflammed sigmoid colon was resected with immediate control of the hemorrhage. Pathological examination of the resected colon revealed active Crohn's colitis. Massive hemorrhage in Crohn's disease is uncommon and is quite unusual for it to be the initial manifestation of this disease. Review of the literature reveals that this patient may be the oldest reported patient to have suffered a massive gastrointestinal hemorrhage as the initial manifestation of Crohn's colitis. Regional enteritis should be considered in the differential diagnosis of massive rectal bleeding in the elderly patient even if there is no history of Crohn's disease.

Massive rectal bleeding in the elderly patient has a number of causes including diverticular disease, vascular ectasias, and ischemic colitis. Inflammatory bowel disease, specifically Crohn's disease, is not usually considered in the differential diagnosis. Documented cases of massive rectal bleeding from Crohn's disease are few, especially with disease limited to the colon.

Case Report

A previously healthy 89-year-old female was admitted with a one-day history of brisk rectal bleeding. She gave a three-month history of occasional bloody stools but had no other complaints. Her past medical history was noteworthy for an admission in 1957 for uncomplicated diverticulitis.

At admission the pulse was 110 and the blood pressure was 120/90 mm/Hg. The abdomen was slightly distended with mild tenderness in both lower quadrants. No peritoneal signs were present. Sigmoidoscopy to 15cm. revealed normal mucosa and blood in the rectum with no bleeding point seen. The hematocrit was 25%. A platelet count, prothrombin time, partial thromboplastin time and a bleeding time were normal.

Two units of blood were administered. A bleeding scan revealed active bleeding in the sigmoid colon. (Figure 1) Angiographic control of the bleeding point was attempted but the inferior mesenteric artery could not be cannulated.

The patient continued to bleed, requiring eight units of blood as well as fresh frozen plasma and platelet transfusions over the next eight hours. An emergency laparotomy was deemed necessary to control life threatening hemorrhage. At operation an inflamed, edematous, thickened sigmoid colon, which grossly appeared typical of Crohn's colitis, was found. Fat wrapping and a localized area of ecchymosis were noted in the serosa. Scattered diverticuli were also seen in the left colon. The rest of the colon and the entire small bowel revealed no other areas of inflammation. A resection of the grossly involved sigmoid colon with an end colostomy and a Hartmann's pouch was performed. The patient recovered uneventfully and had no further bleeding.

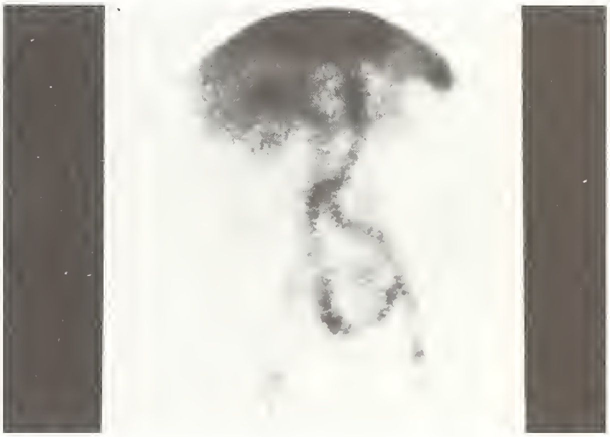

Figure 1

Gastrointestinal bleeding scan demonstrating an arcuate band of activity in the lower pelvis consistent with active GI bleeding from the rectosigmoid colon.

The resected colon had a hyperemic serosa without evidence of perforation. The mucosa was flattened in areas and had interrupted patches of ulceration. Polypoid changes were also found in the mucosa. Microscopic examination revealed areas of surface ulceration, transmural ulceration, and fissures. Granulomata, some with multinucleated giant cells, were present. One section had near total necrosis of the bowel

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wall. Pathologic diagnosis was transmural colitis consistent with Crohn's colitis. It was felt that this area of activite, acutely inflamed Crohn's colitis, which corresponded to the area demonstrated by the bleeding scan, was the source of her massive rectal bleeding. The actual bleeding point was not seen either grossly or microscopically.

After a six-month symptom-free interval following her initial operation the patient underwent abdominal exploration and reanastomosis of her colon. There was no visible residual Crohn's disease in the remaining colon or rectum.

Comments

Although many patients with Crohn's disease will have episodes of minor rectal bleeding, massive gastrointestinal hemorrhage in this disease is uncommon. Homan et al[1] found seven cases of massive bleeding in a review of 503 patients who underwent treatment for Crohn's disease in a 40-year period at Cornell Medical Center. In their review they documented another 19 cases of massive bleeding from Crohn's disease, exclusive of Crohn's disease of the stomach or duodenum.[1] Van Patter's series[2] of 600 patients with Crohn's disease from the Mayo Clinic noted that 14 patients had profuse amounts of red blood in their stools, an incidence of 2.5%. Crohn and Yarnis[3] had an incidence of massive bleeding of 1.1% in their review.

Massive rectal bleeding as the initial manifestation of Crohn's disease is unusual. Only one of the patients reported by Homan et al[1] presented in this manner. Rubin et al[4] described eight patients who had massive rectal bleeding from Crohn's disease as the intial manifestation of the disease. Bruyn et al[5] reported four patients with massive hemorrhage as the initial presentation of the disease and a number of case reports have also noted massive rectal bleeding as the first sign of Crohn's disease.[6-19]

Although bleeding is thought to be more common with the colonic form of Crohn's disease[20] there are few well documented cases of massive hemorrhage from Crohn's colitis. Furman et al[21] found two patients in which this occurred. Mellor et al,[22] Bruyn et al,[4] and Renison et al[9] each noted massive bleeding in one patient. The patient described by Renison et al[9] had massive rectal bleeding as the initial manifestation of his illness.

Crohn's disease primarily affects young people[23] and rarely does it present initially in an individual older than 60 years of age.[24] When Crohn's disease does develop in the elderly, the colon may be more frequently involved than other segments of the gastrointestinal tract.[24-26]

The patient described in this report presented with massive hemorrhage and at operation was found to have segmental granulomatous colitis. Surgical resection of the involved colon resulted in cessation of the bleeding and the patient recovered uneventfully. A review of the literature reveals that this individual may be the oldest patient on record who has had a massive rectal hemorrhage as the initial manifestation of Crohn's colitis. Surgical resection may be life saving in the patient with massive hemorrhage from Crohn's colitis.

Summary

A case of massive rectal bleeding that proved to be the initial manifestation of Crohn's colitis in an 89-year-old female is reported. Physicians need to be aware of the possibility of regional enteritis as a cause of massive rectal bleeding in an elderly patient. When uncontrollable hemorrhage from Crohn's colitis occurs surgical resection may be life saving.

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The Localization and Management of Nonpalpable Breast Lesions

JUDY L. SMITH, M.D. AND PETER J. DECKERS, M.D.

Introduction

Mammography has become the universally accepted screening modality for the early detection of breast cancer. It is clearly effective. In the Breast Cancer Detection Demonstration Project 50% of the breast cancers found were detected by mammography only, and 75% of these had negative axillary lymph nodes.[1] With improved technique and increased skill in mammography, a large group of patients have been identified with nonpalpable but significant mammographic abnormalities. The management of these occult lesions presents a dilemma for the surgeon. Early approaches at diagnosis of suspicious lesions involved blind biopsies, often removing large quantities of tissue and leaving a cosmetically poor result. The lesion was also often missed entirely with this method and rebiopsy required. New techniques have been developed for localization of these lesions. Perhaps the most successful and most commonly used technique is preoperative needle localization. This procedure appears to be highly effective as a guide for biopsy of occult lesions and has diminished reluctance to excise nonpalpable breast lesions. It facilitates removal of a smaller segment of breast tissue and allows a cosmetically improved surgical procedure. Significantly, the majority of nonpalpable suspicious mammographic lesions are benign. Based on age, mammographic suspicion, personal and family history, the surgeon must make his/her decision to biopsy or not to biopsy. This review examines these factors in 85 women with nonpalpable lesions all undergoing breast biopsies after preoperative needle localization.

Materials and Methods

At the Hartford Hospital, 85 women underwent breast biopsies with preoperative needle localization for nonpalpable lesions between September 1983 and June 1984. An analysis of the clinical, mammographic, operative and pathological data from each patient was performed utilizing office, operative and hospital records.

Each patient had screening mammography. Reasons for mammography were varied and included a strong family history of breast cancer, personal past history of breast cancer or patient or physician preference as influenced by current recommendations by the American Cancer Society.[1] No patient had a palpable lesion or any sign or symptom of breast cancer. Mammography was done and interpreted by staff radiologists in the Department of Radiology of the Hartford Hospital. The decision to biopsy was made by the surgeon and primary physician based on clinical and mammographic findings.

Needle localization was done under mammographic control on the day of surgery. A hooked wire was placed in close proximity to the lesion in question using the technique described by Frank and others.[2-4] Under local anesthesia a hooked wire is directed through the skin and

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into the suspicious area with lateral and horizontal mammographic visualization. After confirming the accuracy of needle placement, the patient and mammograms were taken to the operating room for biopsy. The surgeon reviewed the needle placement, often in consultation with the radiologist, and used the needle and mammogram as guides for localizing the lesion. The breast tissue was excised and sent for specimen radiography. After confirmation that the lesion was contained within the specimen, the biopsy site was closed. The specimen was then sent for pathologic examination. Frozen section was done in only 7/85 cases. Definitive treatment was deferred until final pathology was obtained.

Results

Twenty of 85 (24%) women undergoing biopsy with preoperative needle localization had a carcinoma. The age of these patients ranged from 34-81 years and the mean age, 55.5, did not differ from those with benign findings. Other demographic features were evaluted and are listed in Table 1. The incidence of a positive family history for breast cancer overall was 23%. Ten percent of those with carcinoma and 28% of those with benign disease had a positive family history. Only one patient found to have breast cancer had a personal history of an antecedent carcinoma of the breast.

Table 1
DEMOGRAPHIC DATA

	Overall	*Cancer*	*Benign*
Age Range	34-81	36-81	34-76
Mean	55	56	54
+ Family History	23%	10%	28%
Estrogens	17%	6%	21%
Premenopausal	17%	25%	15%

In those women with malignancy, 75% had negative nodes at the time of axillary dissection. Ten percent had 1-2 nodes positive and 15% had >4 positive nodes after axillary dissection. Histology of these tumors revealed 65% as infiltrating ductal, 30% were intraductal carcinoma in situ and 5% were lobular in situ carcinoma. Histology of benign lesions was described as fibrocystic mastopathy in all cases.

Mammographic criteria utilized in this series as indicators of malignancy are those classically described: A dominant mass with indistinct or irregular borders, clustered microcalcifications, or "crablike" distortions of a mass. Benign-appearing lesions had symmetrical outlines, with/without "benign" calcification. The incidence of calcifications overall was 59% with no difference between malignant (60%) or benign (58%) groups (Table 2). Suspicious microcalcifications were found in 36% of all lesions; no significant difference was identified between the malignant (30%) and benign (38%) lesions. Macrocalcifications, thought to be benign, were found in 23% of the lesions and were more common in malignant (30%) lesions are compared to benign (20%). In Table 3, it is noted that in those lesions felt to be benign by the radiologist, 29% were malignant. In those lesions which were declared suspicious, 26% were in fact cancer. Of those lesions identified as carcinomas mammographically only 45% were, in fact, malignant.

Table 2
INCIDENCE OF CALCIFICATIONS BY MAMMOGRAPHY

	Overall (%)	*Cancer* (%)	*Benign* (%)
Total	59 (50/85)	60 (12/20)	58 (38/65)
Microcalc.	36 (31/85)	30 (6/20)	38 (25/65)
Macrocalc.	23 (19/85)	30 (6/20)	20 (13/65)

Table 3
DEGREE OF MAMMOGRAPHIC SUSPICION CORRELATED WITH INCIDENCE OF MALIGNANCY

Mammography	*% Positive Biopsy For Cancer*
Benign	29
Suspicious	26
Malignant	45

The technique of preoperative needle localization was found to be very precise with low morbidity. In only three cases was the lesion identified on mammography not found in the excised breast tissue. Two of these cases were due to a failure to localize the lesion. In one case the lesion was not adequately localized, yet the surgeon was able to identify and excise the lesion. There were no cases of post operative wound infections or significant hematoma. No significant cosmetic deformity was reported. Only one patient required prolonged hospitalization (24 hours) and this was due to postoperative nausea.

Discussion

Screening mammography has been shown to be extremely effective in the early detection of breast cancer.[1] According to the Breast Cancer Detection Demonstration Project (BCDDP), 40% of breast cancer might be found in a preclinical stage in adequately screened women[1,5] Biopsy of nonpalpable mammographic lesions using preoperative localization reveals a 16-32% incidence of carcinoma.[6,7] These preclinical, nonpalpable carcinomas are smaller cancers with fewer nodal metastasis. Nonpalpable lesions have 6-17% incidence of nodal metastases as compared to 40-60% incidence in palpable carcinomas.[6,7] Stage I carcinoma has a 10-year survival of 75% whereas stage II disease decreases to 25%.[6] Thus, early detection of breast cancer is important if survival is to be improved. Our results are comparable to the current literature with a 24% incidence of carcinoma overall but a 25% incidence of positive nodes.[8-12] Histologically our data are also similar with a majority of the malignancies identified as infiltrating ductal cancer.

Preoperative needle localization offers a precise and safe technique for excision of nonpalpable lesions. Small amounts of tissue are removed, producing a cosmetically improved surgical wound. Complications are rare and the procedure can be performed easily as an outpatient in the majority of cases. Reoperation is rarely necessary if specimen radiography is used to confirm that the lesion has been excised. Frozen section is not advocated. No harm has ever been documented when definitive treatment is delayed. Thus, screening mammography followed by preoperative needle localization and biopsy of a nonpalpable lesion appears to be the treatment of choice currently for early detection of carcinomas of the breast.

The dilemma as to which lesions need to be biopsied remains unanswered. Of the 85 patients who underwent screening mammography in this series, there were no significant demographic features to distinguish them from either the general population or between benign or malignant pathologic groups. Age, family and personal history were not valuable as prognostic guides. It therefore appears that these characteristics should not be used in the decision against biopsy.

Mammographic findings also influence the surgeon's decision. This review differs from much of the current literature for palpable and nonpalpable disease. Snyder describes 63% of occult cancers and 23% of benign lesions having calcifications as compared to our series in which 60% of cancer and 58% of benign lesions had calcifications.[13] Microcalcifications are considered high probability indicators for malignancy; Meyer found an incidence of 60% in occult cancers.[8] Our data suggest no difference in the incidence of calcifications, micro or macro, between benign and malignant lesions. Three factors could be identified to explain this variance from other reviews. Patient selection for biopsy relies heavily on the mammographic features. In no study were all lesions biopsied. Thus, the institution's bias will be projected into the data. Smooth, symmetrical, "benign"-appearing lesions, even with calcifications, may be biopsied less frequently, thus accounting for the lower incidence of calcifications in benign lesions in Snyder's series. Meyer's review may have preoperatively eliminated many patients without calcifications due to common beliefs that lesions such as these are more likely to be benign. Our data could also be biased in a similar manner. Many of the characteristics which lead to a biased patient group at biopsy have been delineated through review of mammograms in patients with palpable lesions. It appears likely that mammographic features characteristic of palpable carcinomas may not be applicable to nonpalpable lesions. Thus, microcalcifications in nonpalpable lesions is not an absolute indication that malignancy exists. In fact, the majority of such calcifications are benign in our series. A third factor which is likely to play a role in the discrepancy among reviews is the difference in radiologic interpretation of mammograms.

The radiologist's suspicion of malignancy was not found to be highly accurate. In benign-appearing lesions 30% were in fact malignant and in mammographically-malignant lesions more than 50% were in fact benign. A reasonable explanation for this is that the classic mammographic criteria utilized for identifying malignancies in palpable lesions is not completely acceptable for nonpalpable lesions. A more aggressive use of biopsy after appropriate localization seems appropriate.

Conclusions

Preoperative needle localization is an excellent adjuvant to biopsy for the early diagnosis of breast cancer. It is accurate, safe and provides a cosmetically satisfactory result. In those patients who are screened with mammography in a community setting, demographic factors do not appear to be a valuable guide for the surgeon in his/her decision to biopsy patients with nonpalpable lesions. Thus, until further clarification of occult lesions and their mammographic appearance occurs, it is our recommendation that all nonpalpable lesions found on routine mammography be biopsied. Preoperative needle localization offers a valuable aid to biopsy, enabling early detection and treatment of breast cancer.

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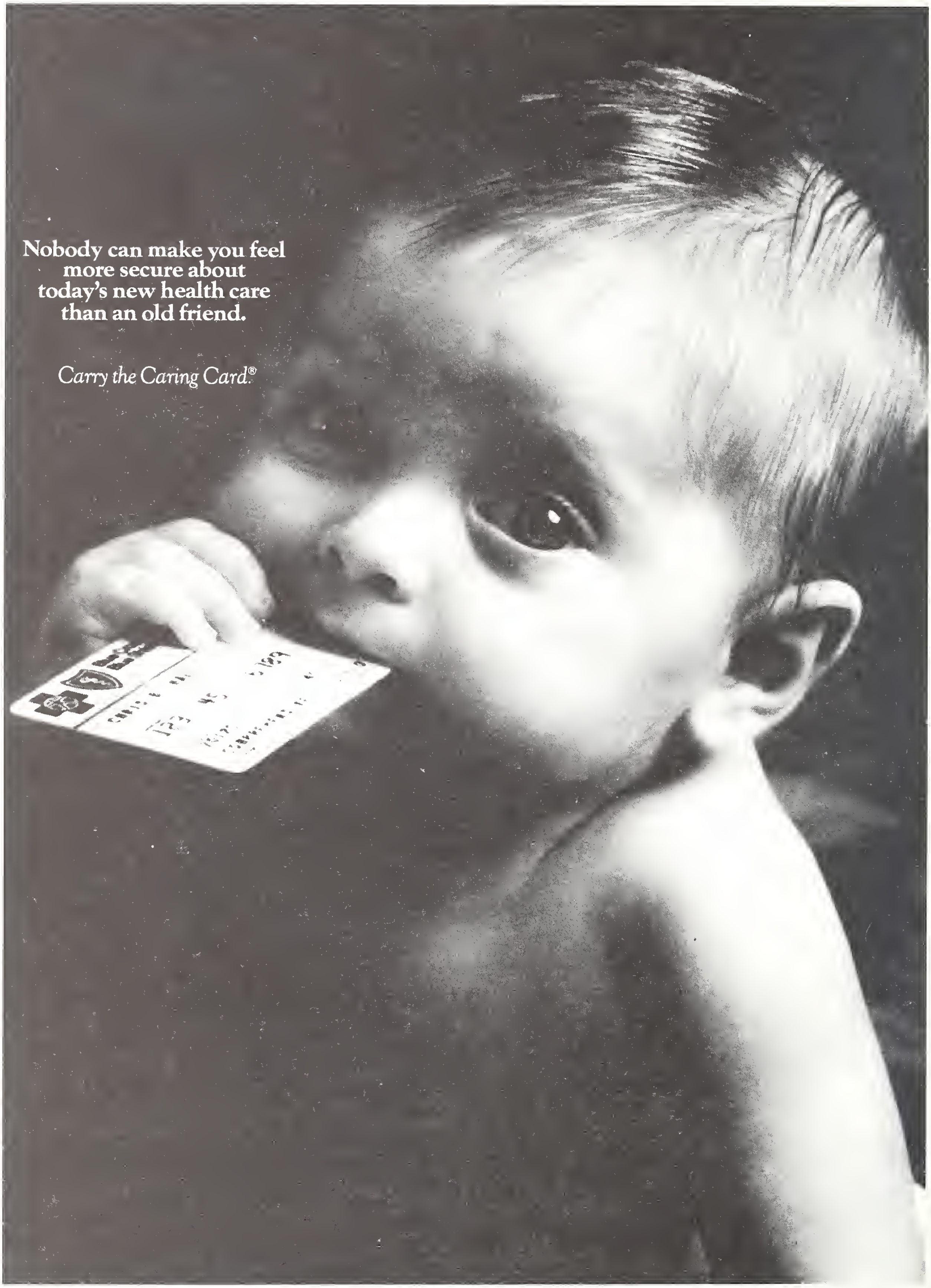
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Diagnosis of Intestinal Carcinoid Tumor by Bone Marrow Biopsy

AURELIO ARIZA, M.D., PINCAS BITTERMAN, M.D. AND IRWIN NASH, M.D.

ABSTRACT— A case of intestinal carcinoid first diagnosed by bone marrow biopsy is presented. The patient was being evaluated for diarrhea and an abdominal mass. A percutaneous thin needle biopsy of this mass was interpreted as consistent with lymphoma. Subsequently, a bone marrow biopsy revealed a single well-circumscribed focus of uniform epithelioid cells interpreted as metastatic carcinoid. A biopsy obtained in the course of an exploratory laparotomy confirmed the carcinoid nature of the intraabdominal lesion.

The literature contains no description of cases of intestinal carcinoid initially diagnosed by bone marrow biopsy. As illustrated by this report, carcinoid tumor should be included in the wide range of non-hematological neoplasms for which a bone marrow biopsy may occasionally provide the histological diagnosis.

Introduction

Pre-operative diagnosis of carcinoid neoplasms in the absence of the typical clinical syndrome is rare.[4] Also an oddity is the finding of metastatic carcinoid tumor in the bone marrow.[3]

We report a patient in whom aspiration cytology of a midabdominal mass was suggestive of lymphoma. This prompted a bone marrow biopsy which demonstrated a single focus of metastatic carcinoid tumor. Exploratory laparotomy revealed a large mass in the mesentery of the small intestine and two liver nodules composed of carcinoid cells. To our knowledge, there is no precedent in the literature of an intestinal carcinoid being diagnosed by bone marrow biopsy.

Case Report

A 64-year-old Caucasian male was admitted for evaluation of an abdominal mass and diarrhea after meals, both present for at least seven years. Upper gastrointestinal series with small bowel follow-through and barium enema were repeatedly negative. Until the present admission the patient refused any further studies and the nature of the mass remained unidentified. Just prior to admission, an abdominal ultrasound demonstrated a 5x3 cm, solid, midabdominal mass and a questionable lesion in the liver. A CT scan disclosed similar findings. An upper gastrointestinal series with small bowel follow-through was negative.

On admission, physical examination revealed a healthy-appearing male in no distress. His abdomen showed a ballotable, firm, non-tender, sausage-shaped mass in the epigastrium. Lymphoma or carcinoma was the diagnosis favored by the clinicians at that time.

During the hospital course, a flexible sigmoidoscopy demonstrated no lesion. A gallium and a liver/spleen scan were within normal limits. A percutaneous needle aspiration biopsy of the abdominal mass was interpreted as suggestive of malignant lymphoma. Subsequently, a bilateral iliac crest bone marrow biopsy disclosed a small well-circumscribed nest of epithelioid cells interpreted as characteristic of metastatic carcinoid. The patient was taken to the operating room for exploratory laparotomy. A large mass extending from the retroperitoneum into the mesentery of the small intestine and two liver nodules were visualized. One of the liver modules was biopsied and found to be positive for carcinoid tumor. No surgical resection of the mass could be performed. Clips were placed around its borders and the abdomen was closed. Postoperatively, the patient was started on chemotherapy.

Results

The needle aspiration biopsy of the midabdominal mass revealed many clusters of small, round, slightly pleomorphic cells with a granular chromatin pattern and scanty cytoplasm. These cells were considered to be atypical lymphocytes and a diagnosis of lymphoma was suggested.

The bone marrow biopsy (Figure 1) disclosed a single well-circumscribed microscopic focus of relatively uniform, Grimelius-positive epithelial cells surrounded by a thin firbrous septum interpreted as consistent with metastatic carcinoid, the diagnosis of lymphoma being

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definitely excluded. No abnormal findings were present in the bone marrow aspirate.

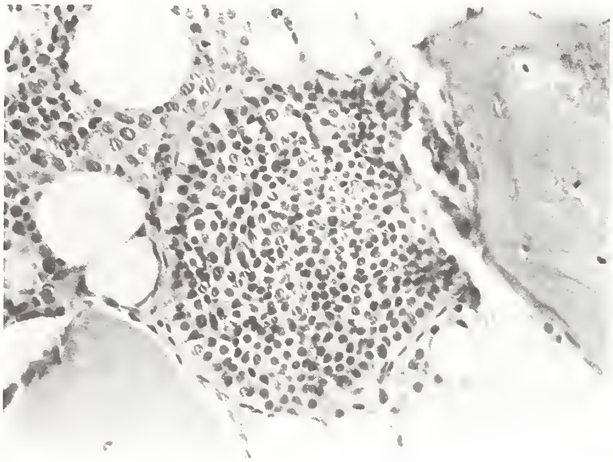

Figure 1

Bone marrow biopsy showing a single nest of uniform epithelial cells interpreted as carcinoid tumor. Hematoxylin and eosin (x400).

The needle biopsy obtained at laparotomy from one of the two liver nodules (Figure 2) demonstrated multiple nests of cells morphologically identical to those seen in the bone marrow biopsy. These nests were surrounded by thick fibrous septa which obliterated the hepatic parenchyma.

Discussion

Bone marrow biopsies are frequently used for the staging of known primary tumors. On the other hand, they may also be performed in the pursuit of a histological diagnosis in patients with suspected malignancy.

Carcinoid tumor metastases are most common in the regional lymph nodes, liver, and skeleton, in that order. Extraabdominal metastatic spread is unusual from midgut origin, as compared to foregut or hindgut origin. Approximately 4% of carcinoid tumors of gastrointestinal origin have evidence of bone metastases.[1] Both osteoblastic and osteolytic metastases may occur in the same patient.[2] Very often, widespread bone metastases are present without producing any bone symptoms,[2] as was true in our patient.

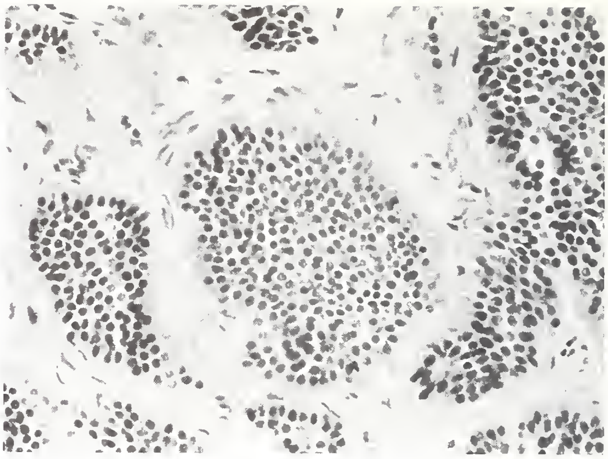

Figure 2

Liver biopsy revealing the presence of metastatic carcinoid tumor. Hematoxylin and eosin (x400).

In the two cases of metastatic carcinoid tumor in the bone marrow seen by Rywlin,[3] the tumor cells appeared in solid sheets, what prompted him to emphasize the differential diagnosis with large cell lymphoma through the use of argentaffin stains. In the case hereby reported, the metastasis was composed of a single circumscribed focus of uniform cells which was readily identified as carcinoid.

The present case illustrates the important role bone marrow biopsy can play in the evaluation of undiagnosed tumors, even in those in which bony metastases are supposed to be a rare event.

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Important Advances in Clinical Medicine

Epitomes of Progress—Obstetrics and Gynecology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in obstetrics and gynecology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in obstetrics and gynecology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Obstetrics and Gynecology of the California Medical Association and the summaries were prepared under its direction.

The NORPLANT Contraceptive System

Hormonal implants for long-term contraception have been studied since 1967. After trials of numerous steroids and delivery systems, it now appears that the NORPLANT system, developed by the Population Council, will be suitable for many women of reproductive age.

The active ingredient is the progestin levonorgestrel, which has been used in certain oral contraceptive formulations for many years. In the NORPLANT system it is continually released into a woman's tissues, and ultimately the bloodstream, from six silastic capsules implanted subdermally into the upper arm and remains effective for at least five years. Its contraceptive action is threefold: inhibiting ovulation (in about 50% of cycles), thickening cervical mucus and suppressing endometrial activity.

Field trials now cover more than 50,000 woman-months of use. Its efficacy is roughly comparable to that of tubal sterilization. In a four-year clinical study by Sivin, the annual pregnancy rate was generally below 0.5 per 100 woman-years and the cumulative five-year pregnancy rate in 992 initial acceptors was 2.7 per 100 continuing users. Fertility promptly returns following removal.

While a newer two-capsule version is undergoing field trials, the six-capsule NORPLANT is likely to achieve approval by the Food and Drug Administration (FDA) earlier because of its lengthier period of study. The six-capsule formulation has been approved for distribution in Finland, where a manufacturer (Leiras) has been licensed. FDA approval is under consideration but the method is not yet approved for use in the United States.

As with all contraceptives based on continuous administration of a progestin, women using NORPLANT frequently experience irregular menses and occasionally intermenstrual spotting or amenorrhea. Break-through bleeding, while considered intolerable by some women, is seldom serious and tends to diminish after the first three to six months. Other side effects usually attributable to steroid contraception occur but tend to be less frequent and severe than with oral steroids because of the low daily dose released by the implants.

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External Cephalic Version

The use of external cephalic version underwent a significant reduction in the early 1970s. Since then, the management of breech presentation at or near term has been by cesarean section and, in selected cases, by vaginal breech delivery. Despite correcting for congenital anomalies, the morbidity and mortality rates for breech deliveries have remained higher for those neonates delivered vaginally than for those delivered by cesarean section. Risks incurred with a vaginal breech birth include umbilical cord prolapse, entrapment of the aftercoming head and birth trauma. Although the alternative of doing a cesarean section for each breech presentation theoretically would re-

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duce the incidence of neonatal morbidity and mortality, it would be at the expense of increased maternal morbidity.

Recently, external cephalic version has been readdressed to reduce the incidence of breech presentations at term. Revisions in the procedure have included changing the timing of the version to 37 weeks or more gestation, the concomitant use of a tocolytic agent during the procedure, preevaluation of the fetus with ultrasound scanning, fetal monitoring before, during and after the version for the detection of fetal distress and doing the version in a hospital with the capability for an immediate cesarean section. The application to more mature fetuses allows for the possibility of a late spontaneous version, minimizes the chances for a spontaneous reversion and decreases the risk for an emergency delivery of an immature fetus. Recent reports have indicated success rates of 55% to 77%, with a very low incidence of either spontaneous reversion or spontaneous version after a failed attempt. The potential risk of external cephalic version includes abruptio placentae, cord entanglement, fetal-maternal hemorrhage, labor, fetal injury or death. The perinatal morbidity and mortality with this procedure is still being evaluated, but preliminary reports indicate it is probably low, with one fetal death in 630 cases.

Contraindications to external version have included the presence of a uterine scar, oligohydramnios, premature rupture of membranes, third trimester bleeding, placenta previa and patients with contraindication(s) to tocolytic agents.

Currently, protocols for doing external version have included the following:

- Informed consent.
- Gestational age of 37 to 40 weeks.
- Doing the version in a hospital with provision for an immediate cesarean section.
- The mother should not eat or drink six to eight hours before the procedure.
- An ultrasound examination to confirm presentation and exclude oligohydramnios, multiple gestations, anomalies and placenta previa.
- A reactive nonstress test before doing the version.
- Administration of a tocolytic agent during the version.
- Continuous monitoring of the fetal heart rate and position with real-time ultrasound during the version.
- Terminate the version if severe maternal discomfort or sustained fetal heart rate deceleration occurs.
- A reactive nonstress test before discharge of the patient.
- Administration of Rh immune globulin to Rh-negative patients before discharge.

Careful adherence to a protocol and patient selection have probably allowed for the current experience of breech version. If the procedure could be confirmed to have a low risk, physicians would have a third alternative to managing cases of breech presentation.

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Vaginal Delivery After Previous Cesarean Section

During the past decade, repeat cesarean sections have accounted for a 30% rise in the cesarean section rate. Motivated by this rising rate, attention has recently been focused on whether vaginal birth after cesarean section is a reasonable alternative to the traditional approach of doing an elective repeat cesarean section. As the evidence has accumulated, a trial of labor or attempted vaginal delivery after a prior cesarean section would appear to be the safer form of obstetric management.

With the option of delivering vaginally after a cesarean section, about 60% of the patients will accept a trial of labor, and 80% of those will achieve a vaginal delivery. Those women with an enhanced probability of achieving a vaginal delivery have had a previous cesarean section for breech presentation, a prior vaginal birth and an infant with a birth weight of less than 4,000 grams.

If a patient elects to undergo a vaginal delivery after a cesarean section, delivery should be done in a hospital. Current criteria include a singleton pregnancy with a known low transverse uterine incision, continuous electronic fetal monitoring, an intravenous line, blood available and a physician available capable of doing an immediate cesarean section. Patients with a fundal incision should not undergo a trial of labor.

The use of oxytocin during the trial of labor should be reserved for those instances where an appropriate indication has been found. When oxytocin is given, adherence to current guidelines is necessary. Under these circumstances, oxytocin may be safely used during a trial of labor and has not been associated with a significant increase in uterine dehiscence or fetal distress. The use of oxytocin, however, is associated with a greater probability of repeat cesarean section (30%) than without oxytocin (10%). During labor, epidural anesthesia may also be used and is not associated with a greater likelihood of repeat cesarean section.

In contrast with those patients not undergoing a trial of labor, the patient who has a vaginal delivery after cesarean section has significantly less morbidity. While the incidences of uterine dehiscence are similar, a patient undergoing a trial of labor has significantly less incidence of febrile morbidity and hysterectomy and shorter hospital stays. But those patients in whom a trial of labor fails and who require a repeat cesarean section have the highest rate of infectious morbidity. In this latter circumstance, the adjunctive use of prophylactic antibiotics would appear to be reasonable.

Another area of concern is the management of a patient with a uterine defect identified after vaginal delivery. Unless the defect involves the uterine fundus, the preferred management at this time would be not to repair the defect. If the patient is hemodynamically unstable or has evidence of persistent bleeding, however, an exploratory laparotomy and repair of the defect should be done. In a subsequent pregnancy in the patient with a known defect, the safety of a trial of labor has not been established.

With an active program of permitting patients with a prior cesarean birth a trial of labor, the cesarean section rate should begin to decline.

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In Vitro Fertilization and Embryo Transfer

The first baby produced by in vitro fertilization and embryo transfer was born in 1978. At that time the procedure had only a 5% success rate, but substantial improvements in our understanding of it have yielded pregnancy rates of 25% to 30% per cycle. Though Steptoe and Edwards originally concluded that the natural cycle produced the greatest chance of success, other investigators have now shown that the "stimulated" cycle is associated with greater pregnancy rates. The Jones program at Norfolk is credited as the first to point out that the greater the number of embryos transferred to a mother, the greater the chance of conceiving (pregnancy rate by transfer: one embryo, 20%; two embryos, 23%, three embryos, 29%). This observation has given rise to a myriad of stimulation protocols using clomiphene citrate, human menopausal gonadotropins (hMG), pure follicle-stimulating hormone or human chorionic gonadotropin (hCG), or all three, to "overstimulate" the ovaries to produce more eggs. Most programs currently use a combination of clomiphene, hMG and hCG. Apparently the risk of the overstimulation syndrome is minimal once follicles are aspirated.

Additional improvements in success rates can be credited to better quality control at the laboratory level. With the development of the mouse embryo assay, items toxic to embryo growth have been identified: glove powder, nonultrapure water, hemolyzed serum supplements and sterilizing rinses.

With the increased number of eggs, and thus embryos produced, increases in multiple-pregnancy rates have occurred. What to do with the "extra" embryos has sparked an interest in cryopreservation technology so the embryos can be stored until transferred in the future during more normal cycles, thus lowering the costs per transfer and decreasing the number of laparoscopies. Contrary to animal cryopreservation successes, however, human pregnancy rates after thawing the embryos have been poor.

Other modifications of in vitro fertilization and embryo transfer have now emerged in attempts to decrease costs and increase success, including ultrasound-guided needle aspiration of follicles and, more recently, the GIFT (gamete intrafallopian transfer) procedure.

THE GIFT procedure, developed at San Antonio, Texas, has similar indications to in vitro fertilization and embryo transfer, except that a patient needs to have at least one patent tube. The ovulation induction and monitoring are similar to those for embryo transfer, except that the eggs once captured and identified are immediately loaded into a transfer catheter, along with a portion of the husband's previously washed sperm, and transferred via laparoscopy or minilaparotomy into the patient's tube. Pregnancy success rates on the preliminary data appear to be around 30% and the cost less than the standard embryo transfer procedure.

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Rh Immune Globulin Update

Although the use of Rh gamma globulin has been widely accepted as an effective method for reducing Rh immunization, there has been considerable controversy concerning its use during the antenatal period. Most physicians agree that administering the material late in a pregnancy further reduces the risk of Rh sensitization when compared with its use only during the postpartum period. The controversy has related to whether or not antenatal administration of Rh immune globulin is cost effective. Much of the immune globulin is clearly wasted because 40% of the pregnancies of Rh-negative mothers result in Rh-negative babies. Geoffrey Tovey has stated that if one uses the material during the pregnancy and the postpartum period, four times as much gamma globulin will be required as compared with its use in the postpartum period only. An alternative to the recommendation of Bowman and others that it be used antenatally in *all* pregnancies has been proposed by L.A.D. Tovey, who recommends that it be used only in primigravid Rh-negative women and in those women who in their first pregnancy were delivered of an Rh-negative infant. The important point to remember is that the greatest risk of stillbirth is during the first Rh-positive pregnancy. Contrary to the thought that was many times expressed in the early literature, the chances of Rh sensitization do not increase with each pregnancy. Although 8% of all "first affected" pregnancies end in stillbirth, the likelihood of death in later pregnancies is much reduced. Tovey asserts that with the plan proposed by him, all Rh-negative mothers can have three live babies.

Although it is my personal belief that the intrapartum use of Rh immune globulin is needed for only the first Rh-positive baby, I have not been able to get other clinicians to adopt this program. The following is a description of the practice used by the obstetricians at Long Beach (California) Memorial Medical Center. The antenatal injection of Rh immune globulin is frequently given in the physician's office. Our recommended protocol is that blood typing and antibody screening be done early in the pregnancy. If Rh-negative, the woman returns at 28 weeks' gestation for a repeat antibody screen. The antenatal Rh immune globulin is then administered. If it was given at 16 to 18 weeks' gestation following amniocentesis for genetic analysis, then a second dose is given at 28 weeks. A record of the antenatal injection is sent to the blood bank at the hospital where the patient's infant is to be delivered. Following the delivery, if the infant is Rh-positive, a postpartum injection of Rh immune globulin is given to the mother within 72 hours of parturition.

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Chorionic Villus Sampling

In the past decade, with the emergence and development of prenatal diagnosis, amniocentesis, because of its safety and reliability, has become the accepted technique for detecting genetic disorders. Despite wide acceptance, alternatives to amniocentesis have been sought because it cannot be done until the second trimester of pregnancy and requires two to four weeks for results to be available. As a result of research in several institutions around the world, a first-trimester method for obtaining fetal tissue specimens, known as chorionic villus sampling, has emerged.

A specimen is taken of the chorionic villus between 9 and 12 weeks from the last menstrual period. Using real-time sonographic guidance, a 16-gauge polyethylene catheter is placed within the chorion frondosum and a small specimen of villi (5 to 30 mg) is removed by aspiration. The villus specimen is placed in culture for cytogenetic analysis or analyzed directly for certain biochemical or DNA studies. In addition, techniques are being developed to obtain chromosome results in as few as 48 to 72 hours.

The indications for chorionic villus sampling are similar to those for amniocentesis and include advanced maternal age, the presence of a chromosomal translocation in one parent, the birth of a previous trisomic child and a family at risk for a specific biochemical or metabolic disorder.

The major complications related to the procedure are spontaneous abortion and infection. Although the risk of spontaneous abortion directly related to the procedure is unknown, preliminary information suggests it to be relatively low (1% to 3%). There also appears to be a slight but significant risk of infection related to the procedure. Included among complications are diagnostic errors, the major sources of error being maternal cell contamination of the specimen. Meticulous attention to dissecting the villi from decidual tissue and careful processing of the material are essential and should minimize this complication.

With more than 3,000 patients now having delivered following chorionic villus sampling, there is no indication of an increased risk for long-term fetal or maternal complications. More complete information on the safety and reliability of this procedure should be forthcoming from the controlled studies now ongoing under the auspices of the National Institute of Child Health and Development. Preliminary experience would suggest, however, that chorionic villus sampling has the potential to become a widely accepted alternative to amniocentesis for detecting genetic disorders prenatally.

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Use of Lasers for the Treatment of Squamous Cell Carcinoma In Situ of the Uterine Cervix

Over the past two decades, the evaluation and management of most cases of carcinoma in situ of the uterine cervix have progressed from a hospital operating room to a physician's office or surgicenter. Diagnostic conization has been replaced by colposcopically directed punch biopsies if the colposcopy is satisfactory and the endocervical currettage elicits no abnormalities. Therapeutic conization or hysterectomy for carcinoma in situ has been replaced in most cases by cryosurgery if the lesion is small and the carbon dioxide laser for medium-sized to large lesions. The carbon dioxide laser has been used in thousands of cases and the success rate exceeds 95% in an experienced physician's hands. The laser beam is used primarily for tissue vaporization but also can be used as an excisional cone to replace the standard cold conization. The indications for laser conization are identical to those for the cold conization.

This "space-age" technique is not without limitations. First, a physician must have mastered the technique of colposcopy. Next, a didactic course in laser principles and techniques with hands-on experience is mandatory. Preceptorships are highly recommended. Because of the potential for harm with inappropriate use, privileges to do the technique must be carefully monitored and granted with the same care accorded major surgical procedures. Instruments are not inexpensive, with costs ranging between $20,000 and $100,000. Consequently, most lasers are found in outpatient facilities or surgicenters. Group or referral practices may have a laser in the office, however.

When doing laser vaporization in the office, local anesthesia is used to eliminate the pain caused by heat buildup. Posttreatment pain is seldom a problem. Exercise is discouraged after therapy to lessen the chance of bleeding. Healing occurs in four to six weeks. Fertility, labor and delivery have not been reported to be adversely affected by the technique.

Unquestionably, laser therapy is an important addition to the management of carcinoma in situ of the uterine cervix, particularly for avoiding the hazards and expense of a surgical procedure.

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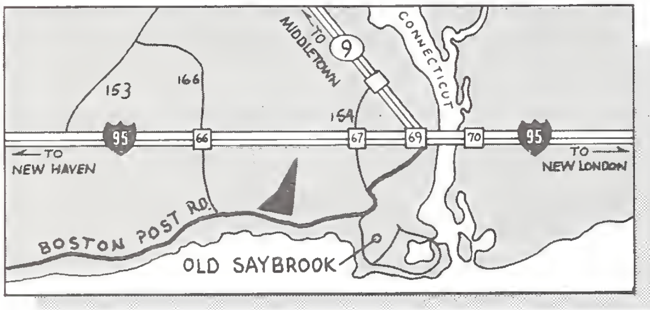

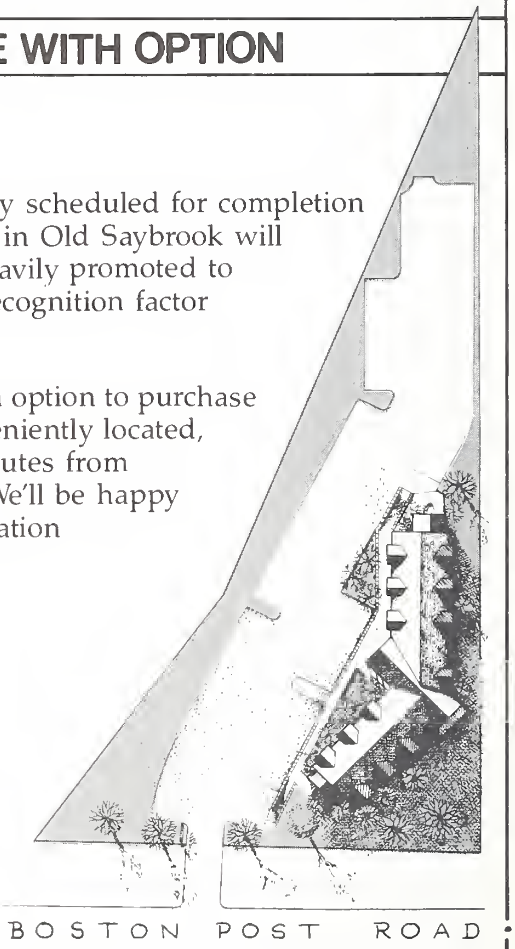

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Medicare Fee Freeze

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Summary and Update

Congress has amended Part B of the Medicare Program to affect the manner and dollar amounts of reimbursement to physicians for services rendered to Medicare beneficiaries. A freeze was imposed on Medicare's determination of "customary" and "prevailing" charges. Further, the fees of "non-participating" physicians—those who will not agree to accept assignment for all services provided to Medicare beneficiaries—were frozen, to control the actual dollar amounts charged by these physicians to Medicare patients.

The freeze originally applied to the period July 1, 1984 to September 30, 1985, and was subsequently extended to March 14, 1986. Future extensions are possible, perhaps even retroactively. For the fiscal year ending September 30, 1986, the "Balanced Budget and Emergency Deficit Control Act of 1985" provides that physicians accepting assignment shall receive a "reasonable charge," less any allowable reduction in the payment amount for services rendered to Medicare beneficiaries (up to 1%). Similar reductions up to 2% are allowed in any subsequent fiscal year.

Two federal trial courts and one federal appeals court have upheld the freeze on fees, and have held that any disparate treatment of non-participating physicians is rationally related to Congress' reasonable objective of curtailing the increase in the federal deficit without placing a burden on Medicare beneficiaries.

The Deficit Reduction Act of 1984 made several changes in the Medicare Program. In particular, § 2306 of the Deficit Reduction Act amended Part B to affect the manner and dollar amounts of physician reimbursement for services provided to Medicare beneficiaries. Prior to these amendments, if a physician elected not to accept assignment of a specific claim, the physician could set his or her charge to the Medicare beneficiary at any fee amount; the patient would receive reimbursement based on the physician's "reasonable charge" as determined by Medicare and would be responsible for paying the physician the difference between the actual charge and 80 percent of the "reasonable charge." In order to determine the dollar amount of the "reasonable charge," Medicare updated "customary" and "prevailing" fee data each July 1, based on the preceding year's data.

The amendments to the Program affect the absolute levels of fees, provide special benefits to "participating physicians" who accept assignment, and provide for monitoring of the fees of "non-participating physicians." Section 2306 amended 42 U.S.C. § 1395u(b) by imposing a freeze on Medicare's determination of "customary" and "prevailing" charges. The freeze was originally to last for "the 15-month period beginning July 1, 1984," freezing fees at the levels set for "the 12-month period beginning July 1, 1983." Thus the freeze on "customary" and "prevailing" charges was to extend from July 1, 1984 to September 30, 1985. The freeze has subsequently been extended by Congress.

Further, physicians are now required to determine before October 1 of each year whether they will be "participating" physicians—i.e., (1) will accept assignment for *all* services provided to Medicare beneficiaries during the 12-month period commencing October 1 and (2) will agree not to charge any Medicare patient on any basis other than assignment (no "balance billing"). A physician who does not elect to become a "participating physician" is a "non-participating physician."

Congress has frozen the actual dollar amounts which "non-participating physicians" may charge the Medicare patients, and this freeze too was extended beyond the original July 1984-September 1985 period. The Secretary of Health and Human Services is mandated to "monitor" the actual charges of "non-participating" physicians to Medicare beneficiaries. "Non-participating physicians" who violate this freeze are subject to civil penalties of up to $2,000 for each violation and may be barred from the Medicare program for up to five years. 42 U.S.C. § 1395u(j)(1), (2). Finally, in determining the "customary" charges of "non-participating physicians" for the 12-month periods commencing October 1, 1985 and October 1,

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1986, Congress directed the Secretary of Health and Human Services not to recognize "increases in actual charges for services furnished" during the freeze period. Actual increases shall be recognized by the Secretary in determining the "customary" charges of "participating physicians," however.

Challenges to the Amendments

Two major cases have challenged the constitutionality of § 2306 of the Deficit Reduction Act. In each case, the amendments to the Medicare Program have been upheld as an appropriate exercise of Congressional authority.

American Medical Association

In *American Medical Association v. Heckler*, 606 F. Supp. 1422 (S.D. Ind. 1985), the American Medical Association, the Indiana State Medical Association, several physicians and several Medicare patients sought to have the federal court declare unconstitutional the statutory amendments providing for the freeze on charges, claiming that: (1) the freeze on the amount that non-participating physicians may charge their Medicare patients discriminates against physicians who treat Medicare beneficiaries, in violation of the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution; (2) as a result of the fee freeze, Medicare beneficiaries could be unable to obtain services from physicians of their own choice, thereby depriving these patients of constitutional rights of privacy, liberty, equal protection, due process, and protection against arbitrary governmental conduct; (3) the government breached a contract with Medicare beneficiaries by not allowing them free choice of physicians and by differentiating the dollar amount of reimbursement that beneficiaries would receive for physicians' services; (4) the Secretary misinterpreted the meaning of "actual charges."

The federal trial court held that the plaintiff Medicare patients had no standing to assert claims (2) and (3) above, since they had not suffered any injury from the freeze. Nor was there any evidence, the court held, that the plaintiff physicians had refused to treat Medicare patients. Since the patients lacked standing, the plaintiff physicians and medical associations were also found to lack standing since they had not shown any independent basis for asserting those claims.

As to the remaining counts of the complaint, the trial court held against the plaintiffs and in favor of the Secretary of Health and Human Services. The court rejected the argument that non-participating physicians were unconstitutionally discriminated against, holding that:

> Congress has reasonably determined that by freezing the customary and prevailing charge levels of participating physicians and by freezing the actual charges of non-participating physicians, it could impose reasonable means of reducing the federal budget without burdening Medicare beneficiaries. Congress' decision to attack the problem of rising medical costs to Medicare beneficiaries by freezing the reimbursement to one group of physicians who accept all Medicare patients on an assignment basis and the actual charges of another group who do not has a rational relationship to Congress' objectives in controlling such medical costs.

Finally, the court determined that the Secretary had not violated the Administrative Procedures Act in her definition of "actual charges for the calendar year beginning on April 1, 1984" and in her interpretation that non-participating physicians may not increase charges to Medicare beneficiaries during the freeze period over the amount charged for the same services during the April 1-June 30, 1984 period.

The American Medical Association and the remaining plaintiffs decided not to appeal the trial court's decision.

Whitney v. Heckler

Three physicians challenged the constitutionality of certain of the § 2306 amendments to the Medicare Program in *Whitney v. Heckler*, 603 F. Supp. 821 (N.D. Ga. 1985), *aff'd*, 780 F.2d 963 (11th Cir. 1986). The freeze amendments were upheld at the trial court level, and this decision was affirmed by the federal Court of Appeals for the Eleventh Circuit.

Plaintiffs sought to enjoin the freeze and asked the trial court for a declaration of their right to raise their fees charged to Medicare patients. The court reviewed the legislation itself and the legislative history of Congress' goal in enacting the amendments. The court reasoned that "Congress did not want the burden of the freeze to be borne by the elderly beneficiaries of the Medicare Program" and that the "temporary freeze" imposed on non-participating physicians' fees "is an integral part of Congress' exercise of its undisputed authority to control federal spending." Moreover, the court held that it was "neither arbitrary nor impermissibly discriminatory" for Congress to adopt "reasonable means of reducing the federal budget without burdening Medicare beneficiaries." The court found that Congress acted reasonably:

> Congress reasonably found that a freeze on federal Medicare payments would harm Medicare beneficiaries unless it also acted to place a cap upon the total fees which could be charged to these beneficiaries by their physicians. Congress also reasonably determined that the interests of Medicare patients would be served if more physicians limited their fees and took cases on an assigned basis. Therefore, it established incentives for physicians to "participate," and agree to take all cases on an assigned basis for a one-year period. These aspects of § 2306 are reasonable in relation to the Medicare program, and were adopted in the interests

of the community. Therefore, due process has been satisfied.

The Court of Appeals affirmed, concluding that the § 2306 amendments allowed Congress to reach its objectives of curtailing the increase in the federal deficit by freezing "customary" and "prevailing" charges and preventing non-participating physicians from "shifting the burden of the freeze to Medicare beneficiaries." After examining the legislative history, the Court of Appeals determined that "the temporary fee freeze provision was carefully drawn in order to accomplish these two objectives." The Court found the "temporary" nature of the freeze to be significant (although noting that the extension of the freeze did not change its "temporary" nature), and that a temporary freeze was reasonable "pending the preparation of a more comprehensive program" which presumably would be based on "a study which can form the basis for more permanent legislation."

Summary

In the *American Medical Association v. Heckler* and *Whitney v. Heckler* cases, the courts refused to enjoin the freeze on fees and held that the disfavored treatment accorded to non-participating physicians was rationally related to Congress' reasonable objectives. Neither case involved a fact situation in which plaintiff Medicare patients could show severe hardship or inability to obtain needed medical services. Absent such circumstances, it seems unlikely that a trial court would be willing to revisit the arguments raised in the *AMA* and *Whitney* cases to reach different conclusions.

AMA Adopts Position on Deficit Reduction Law

The American Medical Association's Board of Trustees adopted a new position on the Gramm-Rudman-Hollings deficit reduction law at its recent meeting in Chicago. The five parts to the position are as follows:

1. The health and medical portion of the federal budget has been targeted for disproportionate cuts over the last five years. The AMA; other groups representing hospitals, nurses, and senior citizens; members of Congress; and government studies all have indicated concern over the impact of past budget reductions and especially over new reductions. Making arbitrary automatic reductions in less than 50 percent of federal spending programs through sequestration is the wrong approach.
2. The entire federal budget for fiscal year 1987 proposed by the President should be closely examined to ensure that the Gramm-Rudman automatic cuts are not necessary. All federal departments and agencies should contribute savings to help achieve the deficit reductions necessary to meet the Gramm-Rudman targets.
3. The AMA should consider supporting a combination of some limited revenue increases and budget cuts as part of a comprehensive program to meet the Gramm-Rudman targets.
4. Gramm-Rudman provisions should be amended so that no federal activity is exempt from automatic Gramm-Rudman reductions. Only about one-half of federal expenditures are subject to the automatic Gramm-Rudman cuts.
5. Gramm-Rudman provisions should be amended to give federal departments greater flexibility within their units.

(AMA Division of Legislative Activities, Department of Federal Legislation and Department of State Legislation.)

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A SOUR VIEW FROM OVERSEAS

European Insurers Give American Litigation-Product Liability Crisis an "F"

JOURNAL OF AMERICAN INSURANCE

Why reinsurers aren't smiling much in London, Paris, or Zurich.

Lest you think that all the recent publicity surrounding the availability of insurance in the U.S. is just so much insurance industry media hype, consider for a moment what the industry's foreign insurer's are saying:

Review Magazine, published by the United Trade Press Ltd., London: "The United States has gone litigation crazy, with the result that liability is becoming uninsurable as reinsurers beat a hasty retreat. Reinsurers (European) are walking away from the United States' unpredictable and imbalanced civil justice system. To say they are disgruntled would be an understatement."

The *Review* saves a few jabs for litigants' expectations:

"Americans do not easily accept fate or the will of God. They are willing to act on their stringent expectations of entitlement, tapping the largest pool of lawyers in the world to file their lawsuits. Lawyers fees exceeded $33 billion in the U.S. in 1983, a threefold increase from 1973. Many Americans regard the civil justice system as a lottery; their lawsuit, regardless of merit, may be the ticket to a big payout. This mentality is pushing the liability system beyond insurable limits."

Lloyd's of London: "The present legal system in the United States makes it impossible for the liability or casualty insurer to operate, certainly to the extent necessary to satisfy the insuring needs of the public; the reason for this is the *total uncertainty facing an insurer as to how the U.S. courts will interpret various policy wordings. (italics ours.)*

UNISON, a worldwide network of correspondent insurance brokers: "...differences in operations, litigation standards and cultural attitudes towards insurance could make many European companies especially vulnerable to the shortage of commercial liability coverage now overshadowing the U.S. insurance market."

Christian Dahms, Jauch & Hubener brokers, Mulheim, West Germany: "The growing number of European companies with modest U.S. operations, or those anticipating start-up or expansion in the U.S., will likely be reluctant to expose their assets to liability exposures that they cannot reasonably insure."

Thus the European insurance market is upset at what is happening in America—especially so since the U.S. litigation crisis is now affecting the operations of European companies who sell their products in the U.S. or who have manufacturing subsidiaries here. The repercussions caused by poor underwriting conditions in this country threaten to jeopardize the ability of these groups to do business in the United States.

Specifically, a number of European industries face severe exposure to loss due to the current shortfall of insurance capacity, including large chemical and oil producers, pharmaceutical and medical supply companies, as well as small to medium-sized businesses with sizable U.S. sales, such as makers of automobile components and other machinery.

Derek Martin, of Willis Faber, a registered brokerage with Lloyd's of London, says that Europeans will probably become more vocal in calling for reforms in the American court system, "particularly anachronistic tort laws that are slowly throttling insurance capacity through unchecked liability awards."

Forced by the unpredictability of the American tort system into a position of being unable to carry uninsured risks, or to afford the price increases necessary to purchase the coverage that is available, many European pro-

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ducers will find their business opportunities seriously threatened in the coming months.

Indeed, over the past year, provoked largely by massive underwriting losses in America, international reinsurers have cut back drastically on U.S. insurance capacity.

"Underwriting intelligently in a climate of burgeoning claims and inflated cash awards by American courts has proven almost impossible and today most foreign underwriters want out of the U.S. market," says Robert V. Hatcher, Jr., chairman and CEO of Johnson & Higgins, an international insurance brokerage firm headquartered in New York.

Citing U.S. Chamber of Commerce statistics, the Johnson & Higgins chairman notes that direct foreign investment in the U.S. has grown nearly 600 percent over the last decade. "Clearly," he says, "overseas investors have a tremendous stake to protect in their U.S. assets."

Aggravating this situation is the fact that European insurers and their buyers have come to depend heavily in recent years on the U.S. market for their coverage, both at home and in their overseas operations.

"Realistically," Mr. Hatcher points out, "we can't as yet say how many companies will stop doing business in the United States because of insurance problems, but we are certain some will have to walk away from opportunities because the cost of doing business and selling products here is prohibitive."

Some of the problems presently facing European insurance buyers:

Among smaller independent or family-owned buinesses with sales or exports to the U.S., product liability insurance has become so expensive as to erase profit margins.

European reinsurers, who now dictate as much as 60 to 70 percent of the total reinsurance capacity worldwide, indicate they will prohibit primary insurers from including even the smallest U.S. subsidiary in the European policy—thus endangering total available coverage of assets.

Compounding the problem are the cultural differences some observers say affect the way in which American and Europeans approach insurance.

Europeans tend to be first-dollar buyers—that is, they generally prefer to have full coverage and are usually uncomfortable with paying high deductibles or even self-insuring losses themselves as their American counterparts have learned to do. Thus, if a European company can't obtain the product liability insurance it needs at a price it can afford, it may be unlikely to want to carry an uninsured exposure on its books—which could, of course, lead to a cutback in operations.

Christian Dahms adds that Europeans' inexperience at shopping around for insurance, relying instead on longstanding multi-year relationships with single contractual underwriters, may make them less adept at coping with rapidly changing adverse conditions in price and cover for their U.S. exposures.

He also cites the strikingly different climate surrounding litigation in Europe, "marked by the absence of contingency fees and the responsibilities of the claimant to pay all court costs if he fails to win his suit." That, coupled with the absence of punitive damages in European courts, "surely leaves many European insurance buyers reluctant to face the prospect of costly liability awards prevailing in the U.S. courts."

On the whole, Mr. Dahms points out, while much of the European capacity crisis is currently being played out in the reinsurance markets of London, Munich and Zurich, "European insurers and manufacturers believe they are dealing with a problem that they have not caused, but that was imported from the United States."

European insurance buyers generally seem to agree that they would fare best in the future by adopting techniques already practiced by their American peers.

"It may have started out as an American problem, but we're all in the same boat now," says Adrian Gregory of Willis Faber. Gregory outlines the practices likely to become more common among foreign insurance buyers: taking higher deductibles, self-insuring more risks at the bottom end of coverage, and ultimately buying whatever umbrella coverage they can afford or find.

Although Johnson & Higgins research indicates that capacity and prices will soften eventually, they assert that current conditions will affect European business for years to come. Learning to live with lower limits and higher premiums should lead many companies to become better versed in the art of risk management. It remains to be seen how much of the change will be for the better—particularly if the unrepentant American civil justice system continues to batter insurers and their policyholders alike.

Effects of Toxic Chemicals on the Reproductive System

AMA COUNCIL ON SCIENTIFIC AFFAIRS

• In an effort to make physicians more aware of the hazards of the workplace to pregnant workers, the Council on Scientific Affairs' Advisory Panel on Reproductive Hazards in the Workplace prepared this third and final report reviewing the effects of chemical exposure. A total of 120 chemicals were considered for reviews based on an estimation of their imminent hazard, ie, widespread use and/or inherent toxicity. Following a brief introduction, which sets out general principles, clinical applications, and aids to the recognition of a human teratogen, the report presents reviews and opinions for three representative chemicals. Information concerning the remaining 117 compounds is available upon request.

Amended Resolution 126 (A-80) of the House of Delegates, "Professional Awareness of Reproductive Hazards to Pregnant Workers," urged the American Medical Association to heighten awareness of physicians about, and to guide them concerning, certain factors associated with the reproductive health of workers and to familiarize them with the "Guidelines on Pregnancy and Work," published by the American College of Obstetricians and Gynecologists. The adopted resolution was referred through the Board of Trustees to the Council on Scientific Affairs.

The Council appointed the Advisory Panel on Reproductive Hazards in the Workplace and requested that the Panel prepare a report. The Panel recommended that the report consider all phases of the reproductive cycle, including male and female fertility, mutagenicity, teratogenicity, fetotoxicity, and postnatal effects. The task was divided into the following three projects: (1) "Effects of Physical Forces on the Reproductive Cycle,"[1] (2) "Effects of Pregnancy on Work Performance,"[2] and (3) "Effects of Toxic Chemicals on the Reproductive System."

The following report on the third project is intended to be a useful guide to physicians. Following an introduction are sections on definitions, general principles, clinical applications, and recognition of teratogens that affect the fetus or infant. Appendix A lists the 120 chemicals that the Advisory Panel studied, Appendix B contains reports on three representative chemicals, and Appendix C is a glossary of terms.

Introduction

In the aggregate, abnormal structural development in human reproduction is not rare. Congenital anomalies severe enough to require some form of treatment occur in approximately 3% to 7% of human births. A variety of factors may contribute to these malformations (Table 1), but there is no recognizable cause for approximately two thirds of the abnormalities.[3] Even the risk of a naturally occurring error in the complex reproductive process is unknown. However, it is known that for about 3% of congenital anomalies the defect may be attributable to drugs or chemicals.

Table 1
CAUSES OF CONGENITAL ANOMALIES*

	%
Maternal metabolic imbalance	1-2
Infections	2-3
Chromosal aberrations	3-5
Drugs and environmental agents	
Radiation	1
Drugs and chemicals	3
Known genetic transmission (autosomal dominant, autosomal recessive, sex-linked recessive)	20
Combinations and interactions	Unknown
Unknown factors	69-73

*Modified from Wilson[3] and reproduced with permission from Academic Press Inc, Orlando, Fla.

From the Council on Scientific Affairs, Division of Personal and Public Health Policy, American Medical Association, Chicago.

Report C of the Council on Scientific Affairs, filed by the House of Delegates of the American Medical Association at the Interim Meeting, December 1984.

This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. This report reflects the views of the scientific literature as of August 1984.

Reprint requests to Division of Personal and Public Health Policy, Council on Scientific Affairs, American Medical Association, 535 N Dearborn St, Chicago, IL 60610 (R. H. Wheater, MS).

Definitions

Agents that create defects in development and growth are known as *mutagens* and *teratogens*. Mutagens affect the offspring by causing permanent mutations that differ from those of the parents. Teratogens affect somatic cell lines or their development, and only the offspring with the affected cell line will be changed. Mutagens involve germ cell micromolecular or macromolecular DNA changes, whereas teratic changes may be evoked by a number of mechanisms.[4] Mutagenic alterations also are a very common cause of teratic changes, but the reverse is not true.

An anomaly or malformation is a primary structural defect that results from a localized developmental error. In contrast, a deformation is a structural alteration of a previously normally formed part.[5] A syndrome is a recognized pattern of malformations, presumably with the same cause but not the result of an isolated error of morphogenesis. Anomalies that occur together more frequently than expected by chance and that do not represent a syndrome are known as an *association.*[6]

General Principles of Teratology

A thorough knowledge of the following principles of teratology defined by Wilson[7] is necessary to understand the cause-and-effect relationship of any agent and its potential to cause a defect. These principles are basic to a hypothesis (Figure 1) that suggests a common pathway for the majority of developmental defects.

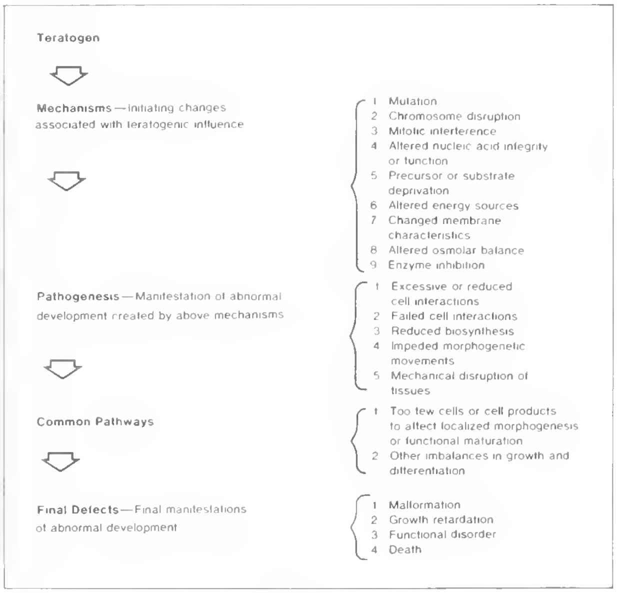
Teratogen
Mechanisms—initiating changes associated with teratogenic influence
1 Mutation
2 Chromosome disruption
3 Mitotic interference
4 Altered nucleic acid integrity or function
5 Precursor or substrate deprivation
6 Altered energy sources
7 Changed membrane characteristics
8 Altered osmolar balance
9 Enzyme inhibition
Pathogenesis—Manifestation of abnormal development created by above mechanisms
1 Excessive or reduced cell interactions
2 Failed cell interactions
3 Reduced biosynthesis
4 Impeded morphogenetic movements
5 Mechanical disruption of tissues
Common Pathways
1 Too few cells or cell products to affect localized morphogenesis or functional maturation
2 Other imbalances in growth and differentiation
Final Defects—Final manifestations of abnormal development
1 Malformation
2 Growth retardation
3 Functional disorder
4 Death

Figure 1

Suggestion for a single or common pathway for developmental defects. (Modified from reference 3 and reproduced with permission from Academic Press Inc, Orlando, Fla.)

1. Susceptibility to teratogenesis depends on the genotype of the conceptus and the manner in which the genotype interacts with environmental factors.

2. Susceptibility to teratogenic agents varies with the developing stage of the fetus at the time of exposure.

3. Teratogenic agents act through specific mechanisms on developing cells and tissues, thus initiating abnormal embryogenesis.

4. The final manifestations of abnormal development are malformation, growth retardation, functional disorder, or death.

5. The access of adverse environmental influences to developing tissues depends on the nature of the influences (agents).

6. Manifestations of abnormal development increase from the no-effect to the totally lethal level as the dosage increases.

Certainly, many mechanisms may control the action of external agents on genetic alterations. These mechanisms are summarized in Table 2.[8] Some chemical compounds may be categorized according to their action on DNA, which allows one to speculate about the mutagenic potential of a compound according to its structure or characteristics. The work of Malling and Wasson[9] provides further information.

Table 2

MECHANISMS INFLUENCING THE GENETIC ACTIONS OF EXTERNAL AGENTS*

- Factors influencing the amount of the agent to which the DNA is exposed
  - Absorption
  - Penetration
  - Transport
  - Activation
  - Inactivation
  - Excretion
  - Condensations of nuclear membrane and chromosome to protect chromosomal DAN
- Specificity of nucleotide kinases and DNA replicases to avoid incorporation of wrong nucleotides into DNA and acceptance of analogues of bases or nucleotides
  - Excision of wrong bases and repair
  - Repair of single-stranded lesions
  - Repair of double-stranded lesions
  - Recombination
  - pH
  - Temperature
  - Removal of mutated cells

*Modified from Freese[8] and reproduced with permission from Charles C Thomas Publisher, Springfield, Ill.

Clinical Application

When a potentially fetotoxic exposure occurs, the outcome may vary from no effect to lethal effect and is determined by a number of factors, including the ability of the toxin or agent to alter normal processes, intensity of the exposure, susceptibility of target tissues, and host resistance. An additional determinant is time, that is, the stage of development of the embryo and the duration of exposure. It is necessary to analyze each of these variables with extreme precision if the patient is to be given useful information. Table 3 and Figure 2 detail the chronology of human development and the organ systems that may

Preembryonic	3rd wk	Cardiogenic area heart tubes form	Oral membrane; head fold will enclose foregut	Neural plate; groove	Intraembryonic mesoderm	Cloacal membrane tail fold will enclose hindgut
Embryonic	4th wk	Heart tubes fuse and loop	Oral membrane ruptures; laryngotracheal groove; pharyngeal pouches; thyroid rudiment; Rathke's pouch; hepatic diverticulum	Neural tube closes primary brain vesicles; cervical flexure, neural crest segments, optic vesicles; lens placodes; otic placodes-vesicles	Limb buds	Nephrogenic cord—nephric ducts
	5th wk	Septum primum; atrioventricular cushions	Olfactory placodes tongue primordia; lung buds tubotympanic; recesses; pancreatic diverticula	Midbrain flexure; spinal nerve roots, otic cups, lens vesicles	Joint flexures, hands and feet	Nephric ducts reach cloaca, ureteric buds reach metanephric blastemas; genital ridges; urorectal septum; genital tubercle
	6th wk	Ostium primum closes; aorticopulmonary septation; cardiac muscle; hemopoiesis in liver	Dental laminae; palatal processes; primitive nasal septum; oronasal membrane ruptures; pleuropericardial canals close; midgut loop herniates cecum/appendix; spleen	Pontine flexure; cerebral hemispheres; nerve plexuses; cerebellum	Chondrification; intramembranous ossification	Mullerian ducts; uretheral plate
	7th wk	Intraventricular septum complete		Choroid plexus; eyelid folds	Skeletal muscle; fingers and toes	Metanephric vesicles; distinctive testes/ovaries cloacal membrane breaks down
	8th wk		Enamel organs; external nares plugged; bronchioles; pleuroperitoneal canals close; smooth muscle		Smooth muscle, endochondral ossification	Mullerian ducts fuse; smooth muscle
Fetal	3rd mo	Hemopoiesis in bone marrow	Nasal septum and palate fusion complete; midgut loop returns	Eyelids fuse		Testes near future internal ring; processus vaginalis; distinctive external genitalia
	Months 4-7		Pulmonary alveoli (6)	Myelination (4); pupillary membrane ruptures (7), Eyelids separate (7)		Vaginal plate (4); canalises (5); testes in inguinal canal (7)

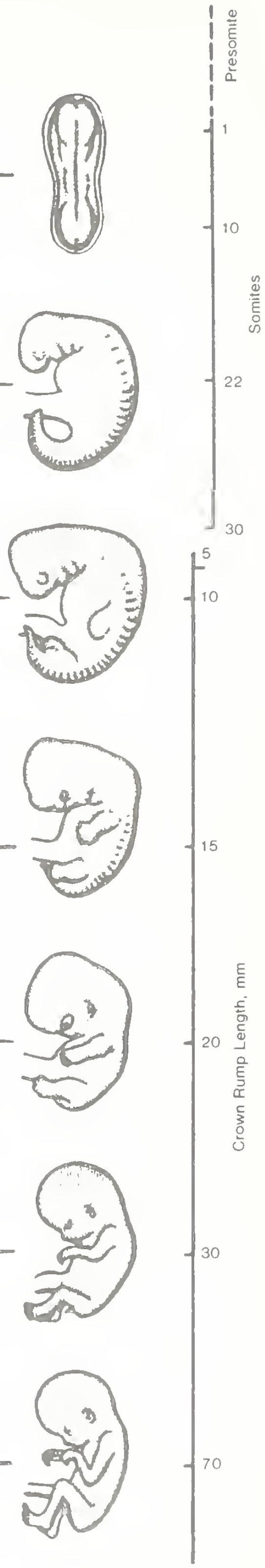

Figure 2

Human organogenesis. Sequence of organ system changes placed on time scale and related to simultaneous changes in other systems. Entries unqualified by verbs refer to first appearance of particular feature. Stage of development at which teratogen is effective may not relate directly to stage at which organ primordia are identified. (Reproduced from reference 10 with permission from Pitman Publishing Ltd. London.)

Table 3
POTENTIAL MALFORMATIONS RELATED TO TIME OF INSULT*

Week Since Ovulation	*Potential Malformation*
Third	Ectopia corids
	Omphalocele
	Ectomelia
	Sympodia
Fourth	Omphalocele
	Ectomelia
	Tracheoesophageal fistula
	Hemivertebra
Fifth	Tracheoesophageal fistula
	Hemivertebra
	Nuclear cataract
	Microphthalmia
	Facial clefts
	Carpal or pedal ablation
Sixth	Microphthalmia
	Carpal or pedal ablation
	Cleft lip, agnathia
	Lenticular cataract
	Congenital heart disease
	Gross septal and aortic anomalies
Seventh	Congenital heart disease
	Interventricular septal defects
	Pulmonary stenois
	Cleft palate
	Micrognathia
	Epicanthus, brachycephaly
Eighth	Congenital heart disease
	Epicanthus, brachycephaly
	Persistent ostium primum
	Nasal bone ablation
	Digital stunting

*Modified from Kaiser [11] and reproduced with permission from Lippincott/Harper & Row, Philadelphia.

be affected at each stage. [11] Other facts that may affect outcomes are described for each compound in the compilation (Appendix A). A short description of what is known about each compound is available from the AMA's Environmental and Occupational Health Program.

The identification of highly mutagenic or teratogenic agents is often a relatively simple task, for the cause-and-effect relationship is usually quite direct. A well-known example is the effect of x-rays. However, the identification of weak teratogens or mutagens may be very difficult because the outcome is less obvious and the defects occur less frequently.

Recognizing Human Teratogens

The following criteria should be present to identify a teratogenic agent in man[3]: (1) an abrupt increase in the incidence of a particular defect or association of defects (syndrome); (2) coincidence of this increase with a known environmental change, such as widespread use of a new drug; (3) known exposure to the environmental change early in pregnancy that yields a characteristically defective infant; and (4) absence of other facts that are common to all pregnancies and that yield an infant with the characteristic defects.

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APPENDIX A

PANEL ON REPRODUCTIVE HAZARDS IN THE WORKPLACE (ALPHABETIC LIST OF ALL CHEMICALS UNDER STUDY)

acetaldehyde
acetamide
acetone
acrolein
acrylamide
acrylic acid
acrylonitrile
Agent Orange (including "2,3,7,8-TCDD")
aldrin
aniline
arsenic
arsenic (penta- and tri-) oxides
benzene
benzo(*a*)pyrene
bromide, potassium
bromide, sodium
butadiene, 1,3-
butanol (aka "butyl alcohol")
cadmium chloride
caffeine
carbaryl
carbon dioxide
ethylene dibromide
ethylene dichloride
ethylene oxide
fluorocarbon-22
formaldehyde
furfural
glycol, ethylene
glycol, propylene
halothane
hexachlorophene
hydantoin
hydrazine, monohydrate
hydrofluoric acid (and inorganic fluorides)
hydroquinone

Kepone
lead (and its salts)
lead, tetraethyl
lindane
lithium carbonate
lithium chloride
malathion
carbon disulfide
carbon monoxide
carbon tetrachloride
cellosolve, ethyl
cellosolve, methyl
chlordane
chloroform
chloroprene, B-
chromium trioxide
2,4,-D
DDT
diazepam
dibenzofurans
dibromochloropropane
dichlorvos (aka "DDVP")
dieldrin
diethyl ether
diethylstilbestrol
  (aka "DES")
dimethyl sulfoxide
  (aka "DMSO")
dimethylacetamide
dimethylformamide, *N,N*-
  (aka "DMF")
dinitroluene
diphenylamine
EDTA
epichlorohydrin
ethanol (aka "ethyl
  alcohol")
maleic anhydride
marijuana
mercuric chloride
mercury (inorganic and
  organic)
methacrylate, butyl
methacrylate, methyl
methacrylates (and
  methacrylic acid)
methanol
methyl iodide
methyl parathion
methylene chloride
methylethyl ketone
naphthalene
nickel
nitrobenzene
nitrogene dioxide
ozone
paraquat
parathion
pentachlorophenol
phthalate, dibutyl
phthalate, diethyl
phthalate, diethylhexyl
phthalate, diisobutyl
phthalate, dimethyl
phthalic anhydride
phthalimide (and
  derivatives)
piperidine, *N*-formyl
polybrominated biphenyls
  (aka "PBBs")
polychlorinated biphenyls
  (aka "PCBs")
propiolactone, B-
resorcinol
rotenone
selenium
styrene
sulfur dioxide
2,4,5,-*T*
TCDD, 2,3,7,8-
tetrachloroethylene (aka
  "perchloroethylene")
thiourea
TMTDS (aka
  "tetramethylthiuram
  disulfide," "thiram")
tobacco
toluene
toluene diisocyanate
toluenediamine
toluidine, ortho-
toxaphene
trichlorethylene
trichloroethane
trimethyl phosphate
turpentine
urethane
vinyl chloride
  (monomer)
xylene

APPENDIX B

ACRYLONITRILE

CAS Registry No. 107-13-1: TLV-skin (ACGIH[1]), 2 ppm; STEL (ACGIH[1]), none; PEL (OSHA[2]), 2 ppm TWA (8-hr), with a 15-minute ceiling of 10 ppm.

Description and Uses

Acrylonitrile is a flammable volatile liquid that can be absorbed through the skin, lungs, and intestinal mucosa. It is used to produce a family of plastics suited to home appliances, boats, and many other applications.[3]

Reproductive Effects

Animal Data. – Groups of 29 to 43 Sprague-Dawley rats were exposed to 40 or 80 ppm of acrylonitrile by inhalation for six hours a day or administered acrylonitrile by oral gavage at 10, 25, or 65 mg per kilogram of body weight from days 6 through 15 of gestation.[4] Maternal toxic reaction was demonstrated at the highest levels in both studies causing a significant decrease in body weight gain. An increase in maternal absolute liver weight was noted at levels of 65 mg per kilogram of body weight. The high levels in each study produced an increase in the number of fetuses with developmental abnormalities (ie, decreased fetal body weight and crown-rump length and increased resorptions and skeletal variations). These findings were statistically significant for only those rats administered 65 mg/kg of acrylonitrile. Rats exposed to 80 ppm or administered 25 mg/kg of acrylonitrile revealed findings suggestive of a teratogenic effect. An exposure level of 40 ppm produced maternal toxic reactions only, while with 10 mg/kg there was no observed effect level.

Stress due to a marked decrease in food consumption in the highest treatment groups during the first three to four days of treatment, which is a very active period of organogenesis, could have contributed to, if not caused, the increased incidence and anomalies observed in the preceding study. Based on the available data, acrylonitrile may be weakly teratogenic in rats at treatment levels that are maternally toxic.

An oral drinking-water study of the reproductive effects of acrylonitrile was conducted using Sprague-Dawley rats dosed at 0, 35, 210, or 500 ppm. Adult rats showed a significant decrease in mean weight gain, food consumption, and water consumption at the two highest concentrations, as well as gastric ulceration (microscopic) and hemorrhage in females at the highest acrylonitrile concentration. Weaning rats exhibited only a slight decrease in growth rate at maternal doses of 500 ppm. At the lowest dose level (35 ppm), the only effect observed was slightly decreased water consumption. No maternal toxic reactions resulted, and there were no effects on reproduction or neonatal growth, survival, or development (Dow Chemical, unpublished data, 1975).

Results of a three-generation reproduction study in which acrylonitrile was incorporated into the drinking water of Sprague-Dawley rats at 0, 100, or 500 ppm showed reduced body weight gain and food consumption at 500 ppm and decreased water consumption at 100 and 500 ppm. Pup survival at 500 ppm was reduced along with the viability and lactation indexes. No gross or microscopic lesions were observed in the tissues of weaning from the third generation. There was no remarkable change in the reproductive performance of rats administered 100 ppm in their drinking water (Litton Bionetics, unpublished data, 1980).

Acrylonitrile has been tested for mutagenic effects in a variety of bacterial and mammalian (in vitro and in vivo) test systems. The results obtained, especially in bacterial systems, have been conflicting, and the data are not adequate for quantitative assessment of mutagenic potential. The mutagenicity tests performed with acrylonitrile do not indicate a consistent pattern of mutagenic activity and suggest that mutagenic activity may be very weak.

Human Data. — No relevant human reproductive data are available.

No increase in the number of chromosome aberrations was noted in lymphocyte cultures of 18 workers exposed to levels of acrylonitrile ranging from 1.5 ppm (1957 to 1977), 5 ppm (1963 to 1974), and unknown (prior to 1963).[5]

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Summary Opinion

Acrylonitrile may be teratogenic in rats at levels that are maternally toxic. Maternal toxic reaction occurred at 40 ppm. There is no evidence to indicate that acrylonitrile exposure presents a reproductive risk.

The Advisory Panel concludes that acrylonitrile does not present a risk to human reproduction at permissible occupational exposure levels.

Arsenic-Inorganic

CAS Registry No. 7440-38-2 (arsenic), 1327-53-3 (arsenic trioxide), 1303-28-2 (arsenic pentoxide): TLV (ACGIH) (arsenic and soluble compounds), 0.2 mg/cu m; STEL (ACGIH), none; PEL (OSHA), 0.01 mg/cu m.

Description and Uses

The source of most arsenic used throughout the world is arsenic trioxide, As_2O_3, a by-product of the smelting of ores for copper, and to a lesser extent, for lead, zinc, and silver. Arsenic is used in making alloys with several metals, in pigment and glass manufacture, and in various inorganic and organic compounds and formulations as an insecticide, fungicide, and herbicide.[1]

The toxicity of arsenic is due to its action as an inhibitor of sulfhydryl enzyme systems.[2] Arsenic is an irritant and sensitizer to the skin and is noted for causing ulcers in the nasal mucous membranes. Epidemiologic studies have shown an excess of lung cancer and skin cancers in humans with chronic arsenic exposures.[3,4]

Reproductive Effects

Animal Data. — Arsenic salts have been reported to be embryotoxic and teratogenic in rodents (hamster, mouse, or rat).[4-6] Results of mutagenicity tests were negative in both prokaryotic and eukaryotic cells.[7] No animal model for arsenic-induced cancer has been found.[4]

Human Data. — Studies for possible adverse effects on human reproductive functions from chronic, low-level arsenic exposures have been confounded by simultaneous exposures to other potentially toxic substances such as lead, sulfur dioxide, and other metallic materials in the effluent from ore-smelting operations.[3,4] Arsenic readily crosses the placental barrier, but studies showing definite adverse effects on the conceptus or neonate were not found. Also, no studies were found on possible adverse effects of arsenic on human fertility or on the gonands.[4]

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Summary Opinion

Arsenic is teratogenic in rodents at doses of about 20 mg per kilogram of body weight, while lower doses have no such effect. Epidemiologic studies in humans for adverse reproductive effects have been inconclusive due to multiple exposures and other confounding variables. Although arsenic is an irritant and skin sensitizer and has been associated with various forms of cancer in humans, the Advisory Panel believes that arsenic is unlikely to have adverse effects on human reproductive functions if exposures are kept at or below the permissible exposure limit.

Carbon Disulfide

CAS Registry No. 75-15-0: TLV (AC-GIH), 10 ppm; STEL (ACGIH), none; PEL (OSHA), 20 ppm (NIOSH recommends a 1-ppm (10-hr) TWA, with a 10-ppm ceiling for any 15-minute period).

Description and Uses

Carbon disulfide is a colorless, volatile, and extremely flammable liquid at room temperatures. Considerable vapor is generated at room temperature. The vapor is 2.6 times heavier than air.[1] It is used in the production of viscose rayon and cellophane and the manufacture of carbon tetrachloride. Other uses include vulcanizing rubber, fumigating grain, chemical analysis, degreasing, dry cleaning, and oil extraction.[2] Carbon disulfide is toxic when the vapor is inhaled or there is repeated skin contact, with the central and peripheral nervous systems evidencing early toxic effects.

Reproductive Effects

Animal Data.—Tabacova et al[3] report that inhalation exposure of pregnant albino rats to 10.0 and 0.03 mg/cu m of carbon disulfide does not produce congenital malformations or functional biochemical changes in the neonate, but 10 mg/cu m affects the postnatal development, causing impairment of viability, retardation of morphological and sensory development, and behavioral deviations (the latter at both exposure levels). These changes were more pronounced in the early postnatal life.[3] In the albino rat, lipid metabolism is also adversely affected in the offspring.[4] Female rats and rabbits were exposed to airborne concentrations of carbon disulfide of 20 and 40 ppm for three weeks before impregnation and up to 30 days after gestation with no evidence of mutagenic or teratogenic abnormalities.[5]

Human Data.—In vitro human cellular studies have not identified carbon disulfide as a mutagen except in one instance of increased frequency of sister chromatid exchanges in cultured human peripheral blood lymphocytes using 10.2 mμg of carbon disulfide per cubic centimeter of medium but not a lower concentrations.[5-7] Adverse effects of carbon disulfide exposure on the reproductive function of both the male and female have been reported. In the female, menstrual abnormalitites, higher incidences of spontaneous abortions, and premature births have been recorded.[1]

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Summary Opinion

The Advisory Panel believes there are significant human and animal data to identify carbon disulfide as being toxic to the reproductive systems of both the male and female as well as the fetus. Prolonged exposure, even at the currently recommended threshold limit value of 30 mg/cu m, might have adverse reproductive effects. There is no convincing evidence that carbon disulfide is a human mutagen or teratogen at the present threshold limit value for regular work exposure.

APPENDIX C

PANEL ON REPRODUCTIVE HAZARDS IN THE WORKPLACE

Glossary

ACGIH.—The American Conference of Governmental Industrial Hygienists was organized in 1938 by a group of governmental industrial hygienists to foster the free exchange of ideas and experiences and the promotion of standards and techniques in industrial health. It is not an official governmental agency. Membership is limited to professional personnel in governmental agencies or educational institutions engaged in occupational safety and health programs.

Ames Test.—A particular in vitro reverse mutation assay system that uses a strain of *Salmonella typhimurium* that lacks the enzyme necessary for histidine synthesis. The assay serves as a quick—results are obtained in three to four days—and relatively inexpensive screening method to determine if a chemical may be mutagenic and possibly carcinogenic. Substances that damage DNA and lead to mutations will cause some of the bacteria to regain their ability to synthesize histidine and to form colonies. The test normally uses five special strains of *S typhimurium*—TA-98, -100, -1535, -1537, and -1538—to detect either frame-shift or base-pair substitution reverse mutation at the histidine locus.

Anomaly.—A marked deviation from the normal standard, especially as a result of congenital or hereditary defects.

Assay.—Determination of the amount of a particular constituent of a mixture or of the biologic or pharmacologic potency of a substance.

CAS Registry Number.—A unique number assigned to a chemical substance by the Chemical Abstract Service; the number serves to identify the chemical among a variety of nomenclature systems.

Chromatid.—One of the two spiral filaments joined at the centromere that make up a chromosome. During cell division they separate, each going to a different pole of the dividing cell and each becoming a chromosome of one of the two daughter cells.

Chromosomal Aberration.—An abnormal chromosomal complement that results from the loss, duplication, or rearrangement of genetic material.

Chromosome.—A structure in the nucleus of a cell containing a linear thread of DNA that transmits genetic information and is associated with RNA and histones.

Conceptus.—The sum of derivatives of a fertilized ovum at any stage of development from fertilization until birth, including extraembryonic membranes as well as the embryo and fetus.

DNA.—A carrier of genetic information for all organisms except the RNA viruses.

Deformity, Birth.—Distortion of a part or general disfigurement of the body.

Embryo.—In animals, those derivatives of the fertilized ovum that eventually become the offspring during their period of most rapid development, ie, after the long axis appears and until all major structures are represented. In humans, the developing organism is an embryo from about two weeks after fertilization to the end of the seventh or eighth week.

Embryotoxicity.—Adverse effects on the embryo as a result of a substance that enters the maternal system and crosses the placental barrier. The effects, expressed as embryonic death or abnormal development of one or more body systems, can also be deleterious to maternal health.

Fetotoxicity.—Adverse effects on the fetus as a result of a substance that enters the maternal system and crosses the placental barrier. The effects usually are deleterious to maternal health and are expressed as fetal death, fetal growth retardation, or retardation of osseous development.

Fetus.—The unborn offspring of any viviparous animal; specifically, the unborn offspring in the postembryonic period after major structures have been outlined. In humans, this occurs from seven or eight weeks after fertilization and continues until birth.

Gene.—The biologic unit of heredity, self-reproducing and located at a definite position on a particular chromosome.

Genotype.—The entire genetic makeup of an individual, the type species of a genus.

Genus.—A taxonomic category subordinate to a tribe (or subtribe) and superior to a species (or subgenus).

Histone.—A simple protein containing many basic groups. The globin of hemoglobin is a histone. Blood treated with histone is altered so that it coagulates with difficulty.

In vitro.—In an artificial environment, or observable in a test tube.

In vivo.—Within a living body.

Mutagen.A chemical or physical agent that induces genetic change in form, quality, or some other characteristic.

NIOSH.—The National Institute for Occupational Safety and Health is an organization created by the Occupational Safety and Health Ace of 1970 within the Department of Health and Human Services. The institute gathers, organizes, analyzes, and disseminates information about injuries and illnesses; recommends new standards; provides technical assistance to workers and employers concerned about job hazards; trains Occupational Safety and Health Administration compliance officers and other safety and health professionals; and conducts workplace health hazard evaluations.

OSHA.—The Occupational Safety and Health Administration was created by the Occupational Safety and Health Act of 1970 and is a part of the US Department of Labor. The agency has the responsibility for establishing and enforcing safety and health standards in the workplace.

PEL (Permissable Exposure Limit).—An exposure level set as a legal standard by the Occupational Safety and Health Administration. It has the same definition as threshold limit value and is mandated as the ceiling level of exposure.

Phenotype.—The entire physical, biochemical, and physiological makeup of an individual as determined both genetically and environmentally.

Postnatal.—With reference to the newborn, occurring after birth.

RNA."Messenger" RNA is a fraction with a base ratio corresponding to DNA of the same organism, which transfers information from DNA to the protein-forming system of the cell. "Ribosomal" RNA comprises about half of the substances of ribosomes, which presumably perform a nonspecific function in polypeptide synthesis.

STEL (Short-term Exposure Limit).—The maximum concentration of a chemical substance to which most workers may be exposed for a continuous time period, not to exceed 15 minutes. Longer exposures may cause severe irritation, chronic or irreversible tissue damage, or a degree of narcosis that might increase accident proneness, reduce work efficiency, or limit self-rescue ability.

Sister Chromatid Exchange.—A crossover between the sister chromatid of a meiotic tetrad or between the sister chromatid of a duplicated somatic chromosome.

TLV (Threshold Limit Value).—A recommended concentration to which most workers may be repeatedly exposed without adverse health effects. "TLV" is a registered trademark of the ACGIH.

TWA (Time-Weighted Average).—A TLV based upon eight-hour workday or 40-hour workweek.

Teras (Plural, Terata).—A "monster." Significant somatic structural defects in a newborn; not heritable.

Teratogen.—An agent or factor that causes the production of physical defects in the developing embryo.

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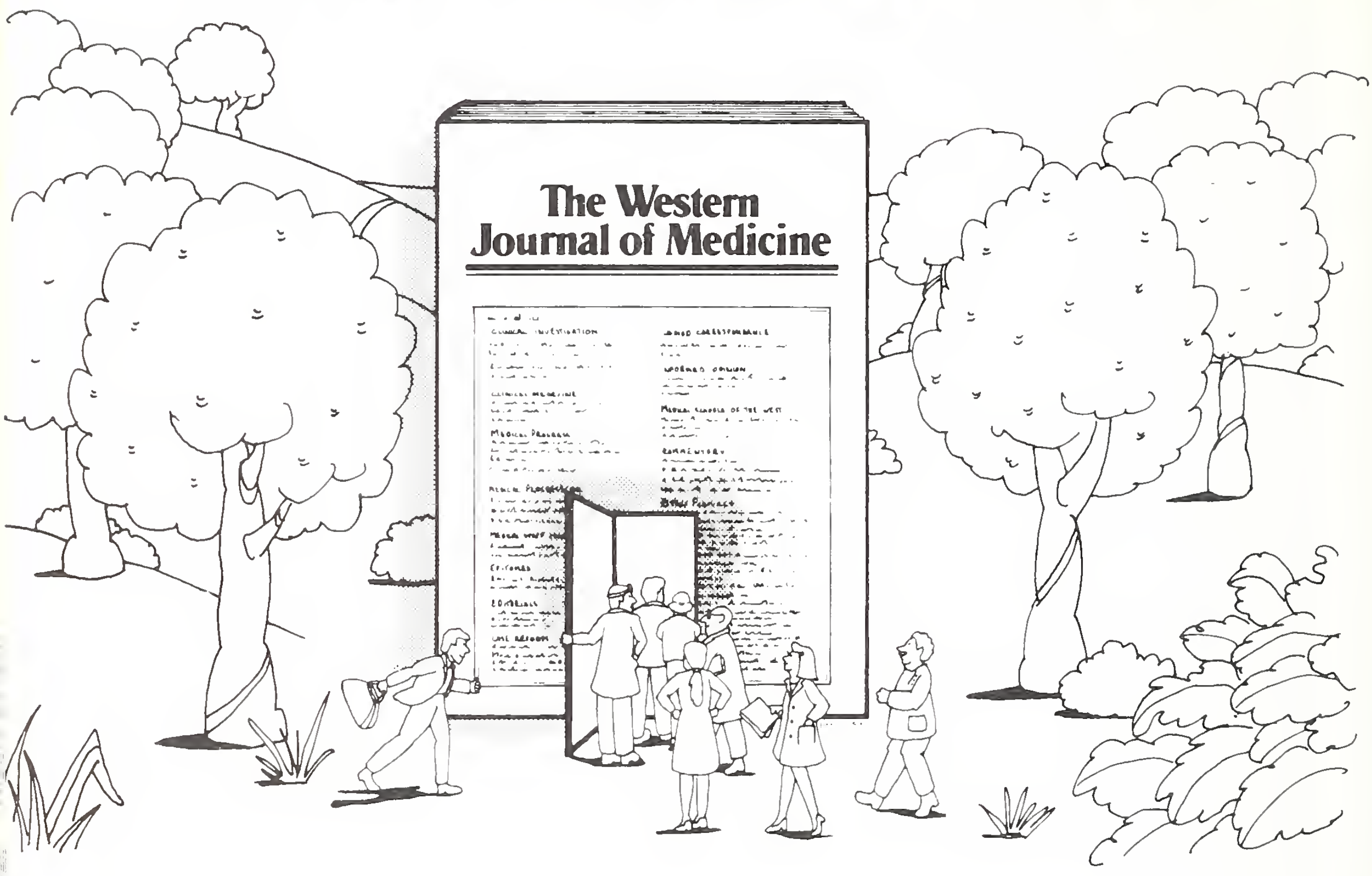
Panel to Study Catastrophic Health Insurance

Health and Human Services Secretary Otis R. Bowen, M.D. named James Balog to head his task force on catastrophic health insurance coverage. The task force will also include representatives of Medicare beneficiaries, health care providers and insurance companies. As part of his advisory group, Secretary Bowen also established three task forces within HHS, one designed to study the need for acute catastrophic care; one to study the needs for long-term care, and a third panel to investigate the needs of the uninsured under age 65. Dr. Bowen still plans to study the issue for one year, as ordered by President Reagan in his State of the Union address in February.

Congress has taken action on catastrophic health insurance in the form of hearings in both the House Ways and Means health subcommittee and the House Aging Committee's health subcommittee, centering on the scope of catastrophic insurance, the role of the federal government and private insurers and financing mechanisms. At least three pieces of legislation have been introduced that approach the issue from a variety of ways: two Health Care Savings Account plans, broadening Medicare to include a Part C for catastrophic coverage, expanding coverage to include treatment for alcoholism and mental health problems, and developing a broad national insurance program for all U.S. citizens that would be financed through taxes on cigarettes and premiums based on income.

Inside Information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Health Implications of Smokeless Tobacco Use

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Smokeless tobacco includes both chewing tobacco and snuff. These products contain tobacco leaf and a variety of sweeteners, flavorings, and scents. In chewing tobacco, the leaf may be shredded (loose-leaf), pressed into bricks or cakes (plugs), or dried and twisted into ropelike strands (twists). A portion is either chewed or held in place in the cheek or between the lower lip and the gum. The two categories of snuff, dry and moist, are made from powdered or finely cut tobacco leaves. In some countries, including historically the United Kingdom, dry snuff is sniffed through the nose, but in the United States both dry and moist snuff are used in the mouth or "dipped." A small amount (pinch) is held in place between the lip or cheek and the gum.

Although smokeless tobacco was widely used in the United States in the past, during this century its use has declined sharply. There is evidence that this trend has reversed, and that smokeless tobacco is regaining popularity. Market data show increases in manufacturing and sales, especially in the category of moist snuff, and total annual sales of smokeless tobacco are now close to $1 billion. Reports from schools in different regions of the country indicate that smokeless tobacco—principally moist snuff—is being used by very young people, especially adolescent males.

Serious questions have been raised regarding health and behavioral effects of use of smokeless tobacco. Most notably, it has been linked to oral cancer. If smokeless tobacco use does produce adverse health effects, then its extensive use could have long-term public health consequences. It is important at this time that the available information be assessed, both to provide the scientific community with a synthesis of current knowledge and a framework for further research and to provide the public with information it needs to make informed decisions regarding use of smokeless tobacco.

To this end, the National Cancer Institute, the National Institute of Dental Research, and the National Institutes of Health Office of Medical Applications of Research convened a consensus development conference on Health Implications of Smokeless Tobacco Use from Jan 13 to 15, 1986. After 1½ days of presentations by experts in relevant fields, a consensus panel including representatives of epidemiology, cancer, dentistry, psychology, pediatrics, psychopharmacology, education, and the public considered the evidence and agreed on answers to the following questions:

1. What are the current trends in the use of smokeless tobacco in the United States?

2. Does the use of smokeless tobacco increase the risk of oral or other cancers?

3. Does the use of smokeless tobacco increase the risk of periodontal disease or other oral and health problems?

4. What are the behavioral consequences of smokeless tobacco use?

5. What issues regarding the health consequences of smokeless tobacco use require further research?

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1. What Are the Current Trends in the Use of Smokeless Tobacco in the United States?—The panel estimates that at least 10 million Americans have used smokeless tobacco within the past year, with 3 million of these users being younger than 21 years. Recent data indicate that significant proportions of teenage boys are current users, and the number of users in this age group is steadily increasing.

Detailed national data on trends in the use of smokeless tobacco are not currently available; however, there are indications of recent significant changes. One such indication is the amount of smokeless tobacco manufactured in the United States. Production declined steadily from 1930 until the late 1960s. Subsequently, there has been a resurgence of production, with a steady increase in total smokeless tobacco output of about one third in the last 15 years, but in just the last five years, the production of moist snuff alone, the form often used by youth, has increased by one third.

The frequency of use of smokeless tobacco has only recently become a subject for national investigation. In 1985, a study based on a nationally representative sample revealed that 16% of males between 12 and 17 years of age had used some form of smokeless tobacco within the past year, and of these, about one third used it one or more times per week. Males older than 21 years of age use somewhat less, with use decreasing for older groups. These figures mask wide variations among subgroups. Only 2% of females use smokeless tobacco, and black and Hispanic males are intermedi-

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From the Office of Medical Applications of Research, National Institutes of Health, Bethesda, Md.

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ate-level users. Patterns of use appear to be similar in most of the country, but with the lowest use in the Northeast.

Some local studies have reported use by 30% to 40% of males in high school; even among third graders, 13% of males have reported use. One study showed for males that use increased at each grade level. Significant use by kindergarten children also has been reported in some areas in one state. In a sample of colleges, about 20% of the males reported use of smokeless tobacco.

In the one local longitudinal study, covering 1976 to 1982, tobacco chewing doubled and snuff dipping tripled, with peak use among boys 12 to 14 years old. It is of interest that in some schools, the percentage of males reporting regular use of smokeless tobacco was higher than the percentage reporting regular use of cigarettes.

2. Does the Use of Smokeless Tobacco Increase the Risk of Oral or Other Cancers?—Observations in humans provide convincing evidence for an increased risk of oral cancer as the result of use of smokeless tobacco. Data on humans are insufficient to determine whether cancers at sites other than the mouth and throat are related to smokeless tobacco use.

Human Data

With respect to human data, a North Carolina study of women provides the most compelling evidence of a role for snuff dipping in the causation of oral cancer. In this study, among nonsmokers the risk of oral cancer was 4.2 times greater for those who used snuff than for those who did not, and for those who were users over several decades the risk was much higher. These data are particularly striking in that (1) the cancer risks were greatest in those locations of the mouth where the snuff was placed; (2) the risk increased with increasing duration of snuff use; (3) factors such as diet, dental hygiene, alcohol intake, and cigarette smoking were found not to be responsible for the association between snuff and oral cancers; and (4) the risks were so large that it would be difficult to postulate alternative explanations for the association between oral cancer and snuff other than a causal one.

These findings are supported by other epidemiological studies, primarily of the case-control type, and by clinical case series. However, most of these studies did not specify the type of smokeless tobacco product, i.e., snuff or chewing tobacco. Thus, it seems prudent to recognize the carcinogenic potential of all smokeless tobacco products, while acknowledging that the effect of snuff has been more fully documented.

Although this relationship has been most clearly demonstrated for elderly, rural women residing in the southeastern United States, there is reason to believe that snuff would also be carcinogenic in women and men in all geographic locations. In fact, men using smokeless tobacco experienced a 3.9-fold increased risk for oral cancer in a study based on the Third National Cancer Survey. Young people, starting the use of snuff in grade school and continuing its use through adult life, are likely to experience comparable risks.

Our conclusion with respect to oral cancer is supported by multiple studies showing a relationship between oral cancer and chewing of betel quid containing tobacco in India and Southeast Asia. Furthermore, the conclusion is consistent with the judgment of a recent working group of the International Agency for Research on Cancer, which reported that the evidence associating snuff with oral cancer is "sufficient" to indicate a causal relationship.

Carcinogens in Smokeless Tobacco

Chemical analysis of various types of smokeless tobacco has revealed the presence of polonium 210, a radioactive alpha-emitter and known radiation carcinogen, and representatives of two classes of powerful chemical carcinogens, the polycyclic aromatic hydrocarbons and the nitrosamines.

Of the 19 nitrosamines identified in smokeless tobacco, the carcinogenic nitrosamines present in the highest concentrations are NNN and NNK, both of which are related chemically to nicotine. Snuff contains 1.6 to 135 mg/kg of NNN and 0.1 to 14 mg/kg of NNK. Loose-leaf and plug tobaccos contain 0.2 to 8.2 mg/kg of NNN and 0 to 1.0 mg/kg of NNK. For comparison, US foods and beverages may not contain more than 0.01 mg/kg of nitrosamines.

Both NNN and NNK readily produce cancer in rats and hamsters in organs such as the nose, trachea, esophagus, and liver. Benign tumors (papillomas) of the mouth are induced when NNN and NNK are applied directly to the mouth of rats.

Carcinogenesis Tests in Animals

Repeated experimental studies in animals have failed to provide adequate evidence that chewing tobacco, snuff, or extracts derived from them induce cancer.

Implications for Human Health

The risk of oral cancer in the United States is small for persons who do not smoke, drink alcoholic beverages, or use smokeless tobacco. The data considered here, however, raise the concern that regular users of snuff, especially children, may develop oral cancer later in life. The panel believes that the public should be warned that the use of smokeless tobacco, particularly snuff, increases the risk of oral cancer.

3. Does the Use of Smokeless Tobacco Increase the Risk of Peridontal Disease or Other Oral and Health Problems?—Evidence supports an association of smokeless tobacco use with gingival recession and oral leukoplakia, but there is insufficient evidence of an association with periodontitis or tooth decay. Other potential physical health hazards are essentially unexplored.

Gingival Recession, Gingivitis, and Periodontal Disease

Both case reports and studies of larger samples show an association of smokeless tobacco use with localized gingival recession (receding gums), especially where the tobacco is habitually placed. One study has reported a significant association of smokeless tobacco use with generalized gingivitis. Data currently are insufficient to support an association of smokeless tobacco use with generalized or advanced periodontal disease.

Tooth Decay

There are disparate data on whether smokeless tobacco use increases or decreases tooth decay. The absence of reliable data that take into account the diversity of smokeless tobacco products and the amount and bioavailability of contained sugars and fluoride may contribute to the lack of agreement among the few reports on this topic.

Leukoplakia

Several reports associate snuff use and, in at least one report, chewing tobacco use with the presence of white patches of the oral mucosa clinically known as leukoplakia. Indeed, leukoplakia is a frequent concomitant of smokeless tobacco use. Although multiple studies describe the malignant transformation of leukoplakia within the range of 1% to 18% of patients over observation periods ranging from several months to 11 years, there are few data on whether snuff-associated leukoplakia per se undergoes similar frequencies of malignant transformation. The studies done to date probably have not been conducted for a sufficient time or with sufficient numbers of long-term users to define the incidence of malignant transformation. Studies from India and Southeast Asia, involving different tobacco products and use patterns, suggest that the long-term risk for malignant change of smokeless tobacco-associated leukoplakia may be significant.

Other Health Risks

Blood levels of nicotine achieved by cigarette smoking, which are similar to those achieved by smokeless tobacco use, cause elevations of blood pressure, heart rate, certain blood lipid levels, and catecholamine values. However, no direct epidemiological data are available on cardiovascular morbidity and mortality in association with smokeless tobacco use.

The complex array of constituents in smokeless tobacco presents a variety of potential health risks for the user as well as for the offspring of pregnant female users. In addition to nicotine, heavy metals such as lead and cadmium have been found in smokeless tobacco at levels that represent potential risks to the fetus and young child.

4. What Are the Behavioral Consequences of Smokeless Tobacco Use?

The Effects of Nicotine

Tobacco produces psychological effects variously described as relaxing, arousing, and euphoriant. Over the past two decades, laboratory and clinical studies have indicated that these effects are mediated by nicotine and blocked by mecamylamine, a drug that competes for nicotine receptors in the brain. Tobacco use leads to a state of dependence in most regular users; this state is characterized by tolerance, physical dependence, and willingness to expend considerable efforts to maintain blood levels within a range of values bonded on the high side by toxic effects and on the low side by the onset of withdrawal symptoms. Blood levels achieved by smokeless tobacco use are similar to those of cigarette smoking. Nicotine self-administration patterns are very similar to those of other central nervous system stimulant drugs in both laboratory animal and human studies.

The abuse liability of a substance—the degree of its ability to gain control over the user—is correlated with the delay between administration and brain levels sufficient to engender a psychological effect. Because nicotine from smokeless tobacco is presumed to reach the brain more slowly than that from cigarette smoke, it might be hypothesized that smokeless tobacco would have lower abuse liability. However, in studies of teenagers who attempted to stop using smokeless tobacco, only a small percentage were able to do so, suggesting that tobacco by the oral route has substantial addicting properties. The continued use of smokeless tobacco even by those who experience serious adverse health consequences attests to its addicting powers.

Addicted users of nicotine become tolerant to the drug; that is, despite experiencing initial unpleasant side effects (eg, tremulousness, dizziness, and nausea), such users increase their dosage until it levels off at one that fulfills their need. Such users seek nicotine continually. Some users of smokeless tobacco use it even while sleeping.

The physical dependence associated with nicotine induces withdrawal symptoms when addicted users abruptly discontinue its use. Thereafter, ex-users often experience craving for nicotine and may become users again.

Other Behavioral Effects

Tobacco withdrawal produces increased irritability and decrements in several basic cognitive functions. These disruptive effects begin within hours of the last nicotine dose. Such cycles of intake and abstinence are typical of use patterns by youths in school and adults in many employment situations. Thus, the associated cognitive impairments could have adverse effects on academic and job performance.

Behaviors can become interchangeable based on their function to the individual. For example, current opinion is that some smokers are switching to smokeless tobacco because the latter is considered a safe alternative for maintaining their nicotine dependence. Others suggest that young people using smokeless tobacco often switch to cigarettes. Use of smokeless tobacco in children is sometimes associated with the use of hard liquor, beer, wine, cigarettes, and marijuana.

Behavioral pharmacology and learning studies show that the determinants of the initiation, maintenance, and reduction of substance use result from the interaction between biochemical and behavioral processes. For smokeless tobacco, nonbiochemical factors that are correlated and readily manipulable include advertisements about smokeless tobacco, influence from peers, parental acceptance of smokeless tobacco use, and perception that smokeless tobacco is less harmful than smoking tobacco.

5. What Issues Regarding the Health Consequences of Smokeless Tobacco Use Require Further Research? —There is a pressing need for well-designed studies of the following:

- Prevalence of smokeless tobacco use based on continuing national probability sample data, including type of product, age, sex, region, and concomitant cigarette smoking. In addition, longitudinal studies should be conducted.
- Users and nonusers of smokeless tobacco products, to characterize better the prevalence and incidence of periodontal disease, caries, leukoplakia, and cancer. These studies should identify, as far as possible, the nature and contents of products used, patterns and duration of use, concomitant use of other substances such as alcohol and smoking tobacco, and occurrence of viral infections. Where appropriate, they should use tissue biopsy as well as critical and laboratory measurements.
- Cancers of sites other than the mouth carried out in geographic areas with high rates of smokeless tobacco use.
- Potential role of smokeless tobacco in cardiovascular disease and adverse outcomes of pregnancy.
- Potential of users of smokeless tobacco to produce nitrosamines in vivo.
- Research on the relationship between amounts of smokeless tobacco used and plasma levels of lead, cadmium, and other potential toxins.
- Strategies for the development and evaluation of prevention programs, including school-based programs, taking into consideration regional, ethnic, age, socioeconomic, and other variables.
- Development and evaluation of early intervention and treatment programs to reduce smokeless tobacco dependence, including a range of approaches based on pharmacological and behavioral treatments. Specific populations that deserve special consideration include (1) school- and college-age persons; (2) persons with specific risk or disease conditions, including malignant and cardiovascular disease, and women at risk for pregnancy; and (3) workplace- and industry-specific populations where elevated smokeless tobacco use is common.

Conclusions

Use of smokeless tobacco has a long history in the United States, but trends in recent years, in particular the increasing use of snuff by children and young adults, have led to concerns about possible health consequences. National data suggest that at least 10 million persons have used smokeless tobacco of one kind or another within the past year. Patterns of use by age, sex, and type of product vary across the country, but prevalence of use overall is relatively comparable.

The human evidence that use of snuff causes cancer of the mouth is strong. Risk is particularly high for parts of the mouth where the snuff is usually placed. Data are currently insufficient to come to any conclusion regarding the relationship of smokeless tobacco use to cancers at other sites. Repeated experimental studies in animals have failed to provide adequate evidence that chewing tobacco, snuff, or extracts derived from them induce cancer. However, nitrosamines chemically related to nicotine occur at high levels in snuff and, generally at lower levels, in chewing tobacco. These compounds are highly carcinogenic in animals. The concentrations of nitrosamines in smokeless tobacco are far higher than the levels of these compounds allowed in any US food or beverage.

Smokeless tobacco use increases the frequency of localized gum recession and leukoplakia where the snuff is usually placed, but evidence on its relationship to other diseases of the oral cavity is inadequate. The presence of lead in smokeless tobacco may pose a special risk for the developing fetus.

Use of smokeless tobacco releases nicotine into the bloodstream and produces blood levels of nicotine comparable with those produced by smoking tobacco. The primary behavioral consequence of regular use of smokeless tobacco is long-term nicotine dependence and its associated health risks.

Use of smokeless tobacco is one of a number of health-endangering behaviors that frequently coincide, raising the clear potential for long-term and serious consequences.

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Adjunct Legal Task Force on Biomedical Ethics

AMERICAN HOSPITAL ASSOCIATION

The Adjunct Legal Task Force on Biomedical Ethics was formed in 1983 by the Office of Legal and Regulatory Affairs of the American Hospital Association and the American Academy of Hospital Attorneys in order to address legal issues in the complex and rapidly changing area of biomedical ethics. The Task Force prepared this analysis of the legal issues involved in the establishment of institutional ethics committees.

Introduction

An institutional ethics committee can be of considerable benefit to a hospital as it struggles with the current complex biomedical ethical environment. Although not a panacea for ethical dilemmas, an ethics committee may provide assurance to patients, the medical staff, the community, and courts that careful, thoughtful, and compassionate decision-making devices exist within a hospital.

Most of the literature on institutional ethics committees contains a paragraph or two on the legal considerations attendant to the establishment and functioning of such committees. These paragraphs generally refer to the confidentiality requirements for medical records, and occasionally to the provision of immunity for committee members. However, the legal aspects of ethics committees are much greater in number and broader in scope than this. It is important that a committee's general purpose includes a discussion of potential issues concerning legal rights or compliance with laws. The committee can use the law to provide it with guidelines in sorting out the often conflicting goals of individuals and society.

This report will begin with a discussion of a hospital's approach to the question of whether an ethics committee may be a useful and desirable mechanism for the particular community or institution. It will then outline the possible functions of a committee, which may be adapted to address identified issues and problems. A discussion of the form and structure of a committee will follow, highlighting the legal issues. The final section will address the various laws which should be considered in order to provide guidance to a committee.

Hospital Approach

There is no legal duty on the part of a hospital to create a biomedical ethics committee. Neither a statutory nor a common law duty exists as yet. The federal government has not mandated the existence of ethics committees in hospitals that receive federal financial assistance, and no state law requires the establishment of such committees. However, the U.S. Department of Health and Human Services (HHS) has encouraged the creation of such committees. The now-invalid final "Baby Doe" rule included model guidelines for the establishment of Infant Care

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Review Committees.[1] Although this rule has been declared invalid in *American Hospital Association v. Heckler,*[2] the precedent for government encouragement of the committee concept, at least in a variation tailored to situations involving seriously ill newborns, has been set. The Child Abuse Amendments of 1984, which include "Baby Doe" provisions, also include language which gives the Secretary authority to develop model guidelines:

> . . . to encourage the establishment within health-care facilities of committees which would serve the purposes of educating hospital personnel and families of disabled infants with life-threatening conditions, recommending institutional policies and guidelines concerning the withholding of medically indicated treatment from such infants, and offering counsel and review in cases involving disabled infants with life-threatening conditions.[3]

No court has indicated that an ethics committee is mandated by any overall legal duty, although an increasing number of decisions have included statements on the subject. Some of these decisions speak favorably of the process of consultation with an ethics committee when there is a difficult case, but others are guarded about such a process.[4] The single instance of an official statement regarding the establishment of ethics committees is the New Jersey Attorney General Opinion which followed the New Jersey Supreme Court decision in the case of Karen Ann Quinlan. However, this decision, advocating intra-institutional discussion of such cases, basically advocated a committee of physicians for the purpose of confirming prognosis rather than a multi-disciplinary committee with a number of different purposes.[5]

In the absence of an affirmative legal duty to create a biomedical ethics committee, hospitals should carefully evaluate the reasons for having such a committee. Although relatively new and untried, ethics committees hold great potential for providing education and guidance, and both the public and the courts appear to be impressed by such careful and thoughtful study.[6] Another reason for establishing a committee may be to provide a forum within the hospital so that it can become the mechanism for bringing together differing views and for mediating the frustrations expressed by all concerned, i.e., patients, families, physicians, and other hospital staff members when dealing with difficult ethical problems.

There may be a myriad of biomedical ethical issues within the hospital which would provide the impetus for development of an ethics committee. Following is a list, by no means exhaustive, of such issues within a hospital:

- DNR orders
- Informed consent
- Patient's right to refuse treatment
- Appropriate withholding or withdrawal of life-support systems
- Implementation of mechanisms valid under Living Will/Natural Death Acts
- Special considerations for infants and minors, and dealing with surrogates
- Advice on implications of new services and technology
- Allocation and use of intensive care unit beds
- Confidentiality/patient privacy and other patients rights issues

A hospital should carefully assess its existing resources, in light of the biomedical ethical issues which demand attention. For example, current hospital structure may include a quality assurance committee, a risk management office, a nursing practices committee, a patient care committee, and medical staff committees which may be looking at one or more of these ethical issues. A patient relations department, attorney's office, and various financial offices which may deal with such issues as scheduling and discharge planning, may be resources on the issues. An ethics committee could provide a central role in the internal coordination of an approach to a particular problem.

Functions

Generally, the objectives of an ethics committee are to provide a forum for discussion of issues and cases, to educate, to prospectively analyze policies and protocols, and to provide advice to and build rapport among medical disciplines.[7] In the current complex medical-technological health care environment, the most important function of an ethics committee may be to educate. By providing educational programs and forums for discussion for the hospital and the community on the importance of integration of medical and ethical issues, the committee can underscore the hospital's commitment to enhancing the knowledge of all concerned about these serious issues. For example, the hard questions surrounding pressure to contain health care costs and resulting allocation of resources will be discussed at the community level, with the understanding that progress to national solutions is the ultimate goal. On the institutional level, staff-oriented programs may be designed to share perspectives on relating ethical principles to specific types of patient cases. When a committee's purposes are to educate and to provide a forum for the airing of differing views, the possibility of alleviating problems or reducing potential liability for the hospital is enhanced.

Another frequently-mentioned function for an ethics committee is as a resource for evaluation and recommendation of hospital policies on biomedical ethical issues. For example, a committee may formulate a policy on do-not-resuscitate orders which would be presented to the board of trustees for approval. A "cookbook" of policies dealing with specific medical situations should be avoided, e.g., for an infant with a specific diagnosis, as such policies may inappropriately intrude upon medical management of a case. However, committee recommendations can help integrate ethical considerations with medical judgments, and may suggest steps in an approach to appropriate decision-making. A cautionary note here—although a committee may be communicating directly with the hospital administration and staff in setting up educational programs and discussion forums, it should be careful to avoid communicating any policy innovation or change directly to the staff absent specific authorization.

The characterization of an ethics committee as a review and consultative body to the decision makers in an individual patient's care, even when it is made clear that the committee has no actual decision-making capacity, must be carefully considered by the board, administration or other body authorizing the committee. Although the benefits of such a committee's function may be considerable, i.e., assurance to the community and to courts that there is a thoughtful decision-making review mechanism within the hospital, the decision to offer consultation of this type must be made with full cognizance of attendant procedural issues.[8] For example, formality of review and mandatory case reporting may lead to implications of affirmative duties in decision-making for both the committee and the medical staff.

Any definition of a committee's function as one of "decision-making" should be avoided. The potential legal implications of such a role include conflict with patient autonomy, appearance of the corporate practice of medicine and the strong possibility of more judicial involvement. There are also questions of greater procedural burdens regarding, for example, access and appeals to the committee. Questions of procedures and structures will be discussed in sections following. In addition, the concept of a "retrospective review" of cases function should be carefully scrutinized. The spectre of after-the-fact fault-finding may be counterproductive to the committee, reducing medical staff cooperation, as well as leading to a "watchdog" approach implying a duty of care on the part of the committee. There are existing committees within the hospital which have responsibility for conducting appropriate reviews.

Form/Structure

A. Authority

A biomedical ethics committee generally may be structured as a committee of either the medical staff or the governing board. The relative merits of one type of committee over another should be analyzed in light of the functions it is meant to fulfill, attendant legal rights and responsibilities and, of course, within the context of the size and kind of hospital considering establishment.

A medical staff-authorized committee raises two threshold questions: what kind of control will the hospital have over such a medical staff committee? and what is the level of liability of such a committee? First, a change in by-laws may be required to authorize such a committee. Second, there may be an effect on the independence of an investigation into the facts of a particular case with this type of committee. However, the confidentiality of patient and committee information may be more easily and effectively preserved within this structure.[9] Finally, the physician-dominated medical-staff authorized ethics committee may become a "prognosis" committee with the purpose of confirming prognosis, but without the broad functions of an institutional ethics committee. The medical staff-authorized ethics committee may not be the preferred structure in light of the reasons for establishing a committee, e.g., achieving a broader focus in approaching issues minimizing liability and providing an open forum for independent discussion.

A hospital committee, i.e. governing board-authorized, may achieve a broader range of desired functions, including education, policy recommendation, and forum for resolution of biomedical ethical issues. For example, a hospital committee can generally reflect a diversity of membership possible with an institutional structure. As such, it may have several benefits in terms of independence and avoidance of bias in its consideration of policies and particular cases, e.g. conflicts of interests on the part of physician members may be minimized. The following section will discuss the implications of such a structure in greater detail. However, it is useful to note that a broad view of an ethics committee's functions to include both community and intra-institutional education and institutional policy-making may generally result in a committee authorized by the governing board rather than the medical staff.

B. Procedural Issues

A biomedical ethics committee should have established, written procedures in order to best achieve its goals. Procedural issues include (1) convening members from a cross-section of the medical staff, hospital governing board and administration, and community; (2) deciding on an appropriate method of meeting on a regular schedule and on response time to issues brought to it; (3) determining who has access to the committee, i.e., who has standing to bring a case to the committee for discussion, and at what times; and (4) establishing a format for meetings and proper methods for handling information both brought to, and released by, the committee.

The procedural issues to be addressed will vary depending upon the functions which the committee will undertake. There may be considerable variation between the procedures for meetings where there is to be consideration of an individual case, and meetings to discuss educational programs or recommendation of policy. For example, different procedures may be desired regarding attendance of members and of "invitees," and methods of taking and recording members' votes when a policy is being recommended versus when a specific patient's case is being discussed.

The problems of keeping committee records and of committee access to patient records are among the most troublesome legal problems confronting an ethics committee. First, the hospital, and the ethics committee by extension, are bound by the customary laws and regulations regarding medical record confidentiality,[10] the length and method of retention of such records,[11] and patient access to his or her own record.[12] In addition, patient or appropriate surrogate consent is required before any confidential patient information may be disclosed to anyone outside of the patient/health care professional relationship. Therefore, an ethics committee with members who are from "outside" the hospital, such as community representatives, may be subject to liability if confidential patient information is used in discussion of a case without patient consent. Also, invitees to a committee meeting, even family members in some cases, may not have access to patient information without consent. In order to circumvent potential problems of this type, a hospital could consider strategies such as extending confidentiality policy to cover non-hospital members of the committee, appointing such members "dollar-a-year" employees who would then agree to a standard oath of non-disclosure, or asking for patient consent on admittance. In any case, a committee should use all possible appropriate methods to keep the patient's identity confidential.

The second consideration of an ethics committee affecting a patient's record is the appropriate recordation of an ethics committee recommendation in that record. A committee's protocols should include how such a recommendation is made and how it is to be recorded, i.e. quorum, voting, and dissent. Hospital policy should be clear as to who will make such an addition, i.e., physician, committee chairman. It should be noted again here that if a committee chooses not to undertake the advisory function, it will not find it necessary to deal with problems of confidentiality regarding a specific patient.

The records or minutes of ethics committee meetings raise questions as to whether such records have any protection from discoverability, and whether they should be open to the public or held in confidence.[13] These are both legal and public policy questions. If confidential patient information is not discussed in committee, then the problem of discoverability fades and the public policy favoring an open process of exchanging information on biomedical ethics rises. If patient information is used in committee discussions, any minutes or case notes should be recorded in such a way as to guarantee patient anonymity.

Immunity of the hospital from liability for committee actions, and of committee members for their actions, are frequently discussed legal concerns. Generally, there are state statutes which provide immunity from civil liability for medical review committee members, and in some states for board of trustee members.[14] These vary considerably from state to state, but generally protect persons involved in committees which evaluate quality of care. An ethics committee may not be protected under such statutes and even read in the best possible light they could provide false security. However, hospitals may wish to propose enactment of a statute specifically immunizing committee members from civil liability, or to structure their insurance appropriately, in the remote possibility that there will be danger to them in establishing ethics committees.

Another important procedural issue is the limit of an ethics committee's jurisdiction. Areas which will not be considered by such a committee should be clearly stated. For example, it may be appropriate to exclude problems of impaired physicians, technology assessment, and institutional review board[14] issues from the committee's topics of concern, since these issues are ordinarily dealt with in other committees. In any case, there should be attention given to proper coordination between an ethics committee and other hospital mechanisms in order to facilitate cooperation and to avoid potentially confusing overlap of responsibilities.

Finally, the role of the attorney must be appropriately structured. A hospital may decide that the attorney who represents the hospital should act as a member of the committee in order to provide legal perspective to committee deliberations when necessary; however, care should be taken to avoid any possible conflict of interest inherent in this arrangement. Another view is that it may be difficult for an attorney to both advise the committee and act as a member. This view would then prompt a structure with an attorney member of the committee chosen from the community, and the hospital's attorney as counsel. It may be unwise for the committee to have its own attorney since it may appear that the committee is not representative of the hospital.

Legal Guidance to an Ethics Committee

There are three broad categories of laws and legal concerns which may aid an ethics committee in fulfillment of the purposes determined for it by the hospital. These categories include societal and legal concerns, prescriptive laws on the state level, and general laws and legal rights best described as those providing guidance on a specific patient's rights. Each of the concerns in these categories will appear in varying degrees of importance when an ethics committee fulfills any of its chosen functions, be it education, policy recommendation, or advisory. However, it is the policy-recommendation function which probably will benefit the most from the examination which follows.

A. Societal Concerns

The impact of societal concerns on the ethics committee of a hospital may not have been considered when forming the committee. However, they provide an important framework for reference for a committee with a broad mandate, especially in the structuring of hospital policies and educational programs.

Medicare and Medicaid are, of course, the clearest examples of society's decision to provide access to care to significant portions of the population. As articulated by government, the programs obviously exert a profound influence over the health of the beneficiaries, and over the financial health of the care providers. Various cost containment strategies practiced by the Health Care Financing Administration in the form of the prospective payment system[16] and by certain state governments in the form of rate regulation programs[17] will certainly continue to affect basic issues of access to adequate health care services. In addition, special programs, such as the federally-funded Hill-Burton program targeted to the provision of care to medically indigent patients, whether sponsored by government on the federal, state or local level or by hospitals alone, are expressions of societal concerns about access to care which an ethics committee should consider.

Another of these societal level concerns is organ transplantation, which can be approached as an example of concern over allocation of resources. Although there is currently no federal law which attempts to systemize the allocation of transplants, the Organ Transplant Act[18] passed in 1984 mandates national-level study on the issue; in addition, some states have addressed the issue.[19] However, there are currently questions as to the kinds and costs of transplants the government or other payers will cover. The questions on the "macro" level involve the appropriate use of hospital resources, e.g., allocation for the benefit of a few specific needy patients, for the benefit of the larger community population in the form of funds for the emergency room, or for the society's benefit in research and development. On the "micro" level, the question of allocation may include which patient will receive an available organ and who will make the decision.

A third example of societal concerns focuses on protection from discrimination on the basis of age, race, sex or handicap.[20] A hospital may wish to empower its ethics committee to consider whether the hospital needs any special policies in order to protect the civil rights of patients and the community it serves.

B. Prescriptive Laws

State laws which define hospital conduct with respect to certain important protections of specified portions of the community are the prescriptive concerns which an ethics committee should note. For example, states have laws defining minority, which may vary considerably as to the ages covered and the definition of who may be considered a "mature" or "emancipated" minor.[21] Of course, the definitions are crucial as to who may be considered competent for the purpose of giving a valid consent to treatment. An ethics committee may wish to consider educational programs or policies which deal with situations where a minor's consent is questioned. Note that this is an area where sensitive parental rights and rights of religious freedom may come into play.[22]

Extremely important prescriptive state laws are those concerning child abuse and neglect prevention and treatment.[23] Although existing hospital procedures to ensure reporting of cases of suspected abuse or neglect may be adequate, education on the issue may be an appropriate endeavor for the ethics committee.

A few states currently have statutes which specifically focus on problems with treatment decisions for handicapped infants.[24] The federal Child Abuse Amendments of 1984 require state child protective agency regulations to expand the definition of medical neglect, adding the withholding of medically indicated treatment as a prohibited element.[25] An ethics committee may wish to formulate special policies to deal with treatment decisions for handicapped infants, and to arrange educational programs on the issue for its community and state child protective service workers.

Finally, a hospital ethics committee should note that there are certain states which have enacted laws to protect specified groups of adults from abuse and neglect. Generally, these laws focus on the elderly, mentally handicapped, or physically disabled adult and on spousal abuse. A Florida statute, for example, establishes a reporting requirement for physicians, nurses, and other hospital personnel when abuse or neglect of these persons is suspected.[26] The definition of what constitutes "neglect" and whether the definition includes medical neglect are examples of issues which concern a hospital, and an ethics committee may aid in the achievement of smooth compliance with such laws through education programs for the staff and the community.

C. Guidance

In this category, laws and legal rights should be considered for their impact upon ethics committee functions as they relate to a patient's exercise of his or her rights. The concern here is the proper implementation of an expression of desire to exercise rights. These differ from the laws described in the "Prescriptive" section which, in and of themselves, mandate conduct. There are two groups of legal concerns in this area: one including broad patient rights and the other addressing a patient's right to choose and refuse treatment.

The first group of legal concerns in this category focuses on basic patient rights, including patient's Bill of Rights and informed consent. It is not necessary to go into these concerns in detail here, but to point out an ethics committee's connection with the protection of these rights. The American Hospital Association published a statement in 1975 titled "A Patient's Bill of Rights" which has been widely quoted and debated.[27] It contains affirmations of basic rights to care, privacy, confidentiality of information, access to information, and to consent to or refusal of treatment. Certain states have codified variations upon this Bill of Rights, which require hospitals to develop policies describing patients' rights and to provide appropriate notice of such a policy.[28] Whether codified or not, it is an appropriate undertaking for an ethics committee to suggest such a document to the policy-making board of the hospital. Informed consent, although primarily the responsibility of the physician, may deserve special consideration by an ethics committee, which may wish to propose procedures to facilitate the process of informed consent to treatment.[29]

The second group of issues focuses on a patient's right to refuse treatment. For example, the establishment of a do-not-resuscitate order policy in a hospital can be aided by an ethics committee, which can ensure that discussion takes place among the staff on the issue and that educational resources be made available to patients, staff and family.[30] An ethics committee may similarly be a facilitator in the smooth acceptance of a patient's desires expressed in a Living Will,[31] or under the aegis of a state Natural Death Act[32] or Durable Power of Attorney Act[33] if one exists. Probably the most important function a committee can undertake in these instances is to provide a forum for discussion in the event that one of these methods of prior expression of a patient is controversial or misunderstood. In this way, exacerbation of a problem situation can be avoided.

Conclusion

As a hospital considers methods of integrating a thoughtful approach to biomedical ethical issues into its internal structure and community relationships, it may focus on an institutional ethics committee as an appropriate conduit to its goals. Although existing committees may be performing some of the functions discussed in this paper, a hospital may wish to centralize the activities in a committee which would help provide education and policy guidelines and be available for consultation. Such a committee could provide support to patients, family and staff. It could also heighten society's view of the hospital as a conduit to responsible decision-making, and be seen as a plus by courts and legislative systems.

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14. See, e.g., Ariz Rev Stat Ann, sec 36-445.02; VA Code, sec 8.01-581.16.
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30. For example, see the DNR guidelines published by the New York State Medical Society.
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Merger: Means to Meet Your Practice Goals?

GEOFFREY T. ANDERS, J.D., CPA, CPBC*, BRAFFORD BAK, J.D., LL.M.
AND LEIF C. BECK, LL.B., CPBC

With medicine being forced from its traditional cottage industry structure, physicians are beginning to explore practice and organizational changes which will hopefully provide security in the changing economic and competitive environment. In the many undertakings being considered—everything from hospital joint ventures to physician provider groups to IPAs—one strong trend we have noticed is the interest in group practice mergers.

Practice mergers can provide a good starting point for dealing with the present and expected changes in the health care business environment.

Practice mergers essentially present a quick avenue to growth and eventual "bigness." That "bigness" will be essential to very successful survival in the years ahead for it provides what many practices lack today—capital for expansion and new ventures, a pool of doctors to draw from for leadership roles, organizational credibility to hospitals, insurers and other big players in the health care game, and most importantly, significant market share. Although those benefits do not automatically flow if, for example, two sole practitioners join forces, the resulting combined practice is one step further along the path to what we perceive will be the desirable practice format for the future.

Choosing a Merger Partner

The choice of a potential merger "partner" is of course critical. Preferable candidates are those practices which (1) are a known quantity in terms of their medical philosophy and scope of practice as well as member physicians' personalities; (2) provide somewhat different services or serve a different geographic market, and (3) at least apparently share similar views on the business direction of medical practice and the health care environment generally. Not all parties to successful mergers have fulfilled these criteria, yet common philosophies, medical and business, as well as complementary practice markets serve as an excellent starting point, improving the overall chances for success.

Preliminary Issues

Upon selecting a "target" for potential merger several threshhold questions need to be addressed.

First, will a merger be legally permissible under the anti-trust laws? While monopolies themselves are not illegal, actively taking steps to *create* a monopoly is. Similarly, any merger which will substantially lessen competition in a given market violates federal law. If there is the slightest chance that an antitrust violation could occur, competent health care antitrust legal advice must be sought. And it may be advisable to seek advisory opinions ("no action" letters) from the Justice Department and Federal Trade Commission. Those letters, if favorably rendered, indicate that the government will take no action and, while not complete protection against a private suit, are strong evidence that the anti-trust laws were not impinged.

Second, the parties should ask themselves and their advisors whether a true merger will best serve the objectives to be attained. For example, we recently consulted two essentially hospital based radiology groups whose only common ground was interest in a particular outpatient market. The basic interests, arrangements, and entanglements of these potential merger candidates were so radically different that it was obvious a merger would not succeed. Instead, a joint venture affiliating the groups solely for servicing the commonly desired outpatient market was proposed and should fit the situation best.

The principal idea here is that although merger may sound attractive there are other approaches that may work better in a specific situation. In various client undertakings originally represented to involve a true merger what has resulted has often been something else—outright acquisitions, group marketing associations, joint ventures, partnerships of professional corporations, and contract medicine entities such as HMOs or PPOs.

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The third question relates to laying the ground rules for future discussions. Parties to merger discussions should enter a "pre-merger agreement" covering such things as cost sharing of merger related expenses, promises not to use information gained in the talks to the other practice's detriment and mutual indemnification from each group's tax, malpractice and other potential liabilities. Along the same lines it may be desirable to initiate a common bank account to fund joint costs related to the potential merger.

Finally, decide on a set of common advisors. These may be "special counsel" retained solely to guide the merger process or the advisors which the group expects to use as an ongoing matter post-merger. Consider beforehand who will be needed. Certainly expert tax, accounting and retirement plan advice is required. Additionally, anti-trust legal help, marketing advisors, insurance advice and general practice management help will often be desirable. Merger gives established practices a chance to critically evaluate and plan how all arrangements of the new group will function—an opportunity not really available when most practices started. That chance should be seized and the best outside help made available so that the restructured practice makes the most of their situation.

Pre-Merger Discussions

Physicians contemplating merger should recognize that such transactions simply do not happen overnight. A good twelve months of hard discussion and work is needed from the time the pre-merger agreement is signed. Doctors should not begrudge this time. It is infinitely better to work out as many issues as possible beforehand than to risk an unacceptable association which must later be dissolved. Time spent up front simply helps eliminate the chance for mistakes and misunderstanding and removes potential problems from the after-merger time frame when the physicians' efforts are needed for revamping practice patterns to fit the new, enlarged group.

All of the doctor members of potentially merging practices need to meet and discuss the prospect. After all, every physician will want to be sure who his or her "partners" are going to be. While total group involvement is important and not to be overlooked, except in solo practice or very small group mergers, every doctor should not participate in discussion of every issue. Thus a representative or at most two representatives should be appointed by each group to keep the "merger committee" to a workable size. Similarly, one of the prime players should be appointed to ride herd on the various outside advisors to be certain that needed advice is available on a timely basis.

Reach accord on the variety of issues—income division, buy-outs, practice decision-making and leadership, entry to co-ownership, retirement policy, permitted vacation and meeting time, sick/disability pay, on-call obligations, etc. A practice merger may be a great business decision, but if the physician members cannot be accommodated successfully, the merged group may not last very long. On the other hand, one or two recalcitrant doctors should not stand in the way of a sensible merger. Often the best way to grow is by subtraction first!

Assuming common footing in terms of medical practice philosophy, perhaps the most critical issue for pre-merger discussion is the mission and future direction for the combined group. Business-wise, where will the practice go and how quickly? Will those directions satisfy the individual doctors' desires, which provided motivation for the merger idea in the first place? Working out this long range business plan prior to merger provides some security and assurance that the post-merger practice will be satisfactory.

Next consider what impact a merger will have within the medical, hospital and patient communities. Will hospital administration or other personnel feel threatened? Will referral sources be gained, lost or remain unchanged? Will patients perceive the move as favorable (more service, better hours, etc.) or unfavorable (too large to receive personal attention). If unfavorable reactions will occur, how can those potential negatives be defused before they impact the combined practice?

Examine how merged practices will function as a practical matter. What hospitals will be covered, how will offices be staffed, what third party insurance arrangements will be appropriate, what billing/collection/accounting system should be used? Will present lay staff be too few or too many? What non-doctor manager or administrator will be needed? All phases of the combined practice should be evaluated and decisions reached to improve patient service and satisfaction as well as business efficiency.

Finally, turn your attention to the actual mechanics of the merger. The basic concern is how to measure each practice's worth and then the means for equalizing the contribution that each party brings to the merger. Practice valuation in this setting principally means defining formulae for application to each practice's hard assets, accounts receivable and goodwill. Occasionally other items will need to be valued also, potentially including particularly valuable below market leases, tax credits and carryforwards, very large supply inventories, real estate and the like.

While valuation generally presents few problems, equalizing each party's contribution can be fraught with difficulty, particularly where very unequally sized practices are involved. This is particularly the case where, despite an agreed upon valuation approach, one side or the other does not like the answer and so attempts to renegotiate the formula. Still, equalizing contributions can be managed. In some cases a predetermined level of cash will be left in one corporation. Or one practice's owners may receive stock plus cash in the merger transaction. Accounts receivable and occasionally goodwill differentials are often handled by income division differentials over the first several years post-merger or even by special buy-out provisions.

Consumating the Merger

From a tax standpoint a properly handled merger is tax free (except for cash or other value received in addition to stock) to the participants. And while the transaction may be technically exacting from the legal standpoint, this rarely needs to be of major concern to the doctors.

Instead there are a huge number of practical matters which require physician attention, both decision-wise before the merger and implementing those decisions after the merger. At least one of the pre-merger practice's names must be changed.

Staff job descriptions need adjustment and often policy manuals, fringe benefit provisions and salaries will require modification to integrate the practices with each other. It is usually not a good idea to leave all lay staff in the same pre-merger office and position. Rather staff should be truly integrated so that as little identification with the pre-merger employing practice and doctors remains. Too much staff loyalty to one practice or doctor can become the wedge which drives a merged group apart.

Similarly, patient charts should be revamped to a single format, stationery and practice signs changed, fee schedules unified and so on. Third party assignment accounts should be brought up to date. Typically the merged group will receive new profiles reflecting their historical changes set at the median fee rate (based on frequency of charges) for the pre-merger practices combined. It is worthwhile to verify that this happens correctly; third parties often err in this calculation so that a watchdog attitude is appropriate.

Discussions leading up to merger are usually kept secret so that no embarrassment occurs if the talks become unproductive. But doctors should plan to take advantage of the marketing opportunity a merger provides. A letter announcement to physicians, hospital personnel, pharmacies and the like should usually precede announcement to patients and the general public. Letting colleagues, especially practice referral sources, know of the merger before others is not only a courtesy but may help avoid doctor complaints that they were "the last to know" or had to "find out from the patients."

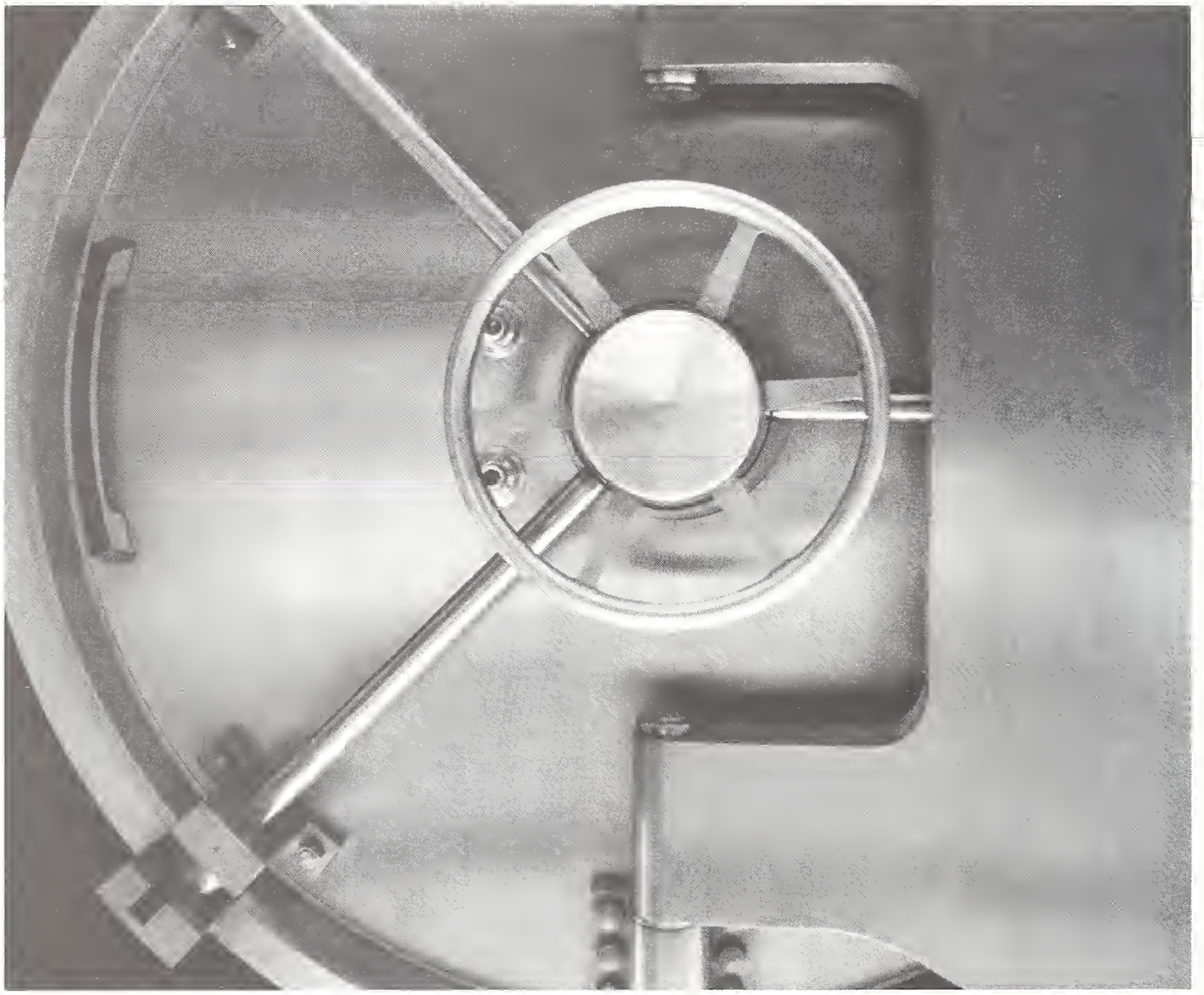
A more extensive letter should be sent to all active and inactive patients. This letter should not only describe the merger but also suggest the benefits to patient care and service which are hoped to flow as a result. Press releases should also be sent to all newspapers both immediately before and after the merger date.

Bail Out Provisions

Even with long, sincere pre-merger discussions and planning, not every merger will be successful. It will be impossible to completely return each group to its pre-merger status quo but, to the extent possible, provision should be made to do that in the event the merged practice falls apart in the initial twelve or twenty-four months of joint practice. Patient charts might be marked to indicate the contributing practice and rules established for the distribution of new patient charts. Inventories of hard assets contributed might also be kept. Original practice telephone numbers might be returned and any new numbers abandoned. Likewise a new practice name adopted upon merger should be "killed" so that no one may benefit from it after a split up. These issues and others need to be addressed up front so that a split up, should it occur, leaves little to be decided when emotions will undoubtedly be running high.

Conclusion

With the health care industry strongly consolidating and the economic environment radically changing, physicians should look to their own future and practice. One potential safe haven lies in larger group practices, leading established practices to critically evaluate the possibility of merger with other groups. With proper planning, merger of practices will most often be successful, hopefully resulting in an enhanced practice situation for physicians and their patients.



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The President's Page

The Holy Grail

In spite of the progressive de-emphasis on the worth of the physician, the doctor still remains the linch-pin of the entire medical system. During the recent trend of merchandising medical care and commercial packaging of physicians services, we as physicians have lost sight of our province, but we are beginning to emerge from our lethargy. We are beginning to appreciate once again the relevance of our existence and our strength. We are beginning to recapture our lost sovereignty!

Heretofore, physicians have been pre-occupied with caring for patients while the business world has been exploiting the practice of medicine. Through data collection, business strategies have been implemented achieving financial gains for entreprenurial intermediaries which exclude physicians from sharing in the profits. Investors anticipate gigantic profits in supporting alternate health care delivery systems. To wit, I refer you to the recent forty million dollar offer of CIGNA to purchase a physician-owned IPA-HMO in Rockville, Maryland. The deal involved 1,200 physicians serving 75,000 patients. Proceeds from the sale of the IPA-HMO would have yielded at least $35-40,000 dollars to each physician who made an initial investment of $1,000. The philosophical issue of losing control was greater than the financial gain to the physician-stockholders, and the buy-out was turned down. Physicians are beginning to awaken from their state of narcosis.

The groundwork for regaining our lost sovereignty in the State of Connecticut was instituted by the formation of the physician controlled CMIC, CPRO, and now the proposed IPA-HMO. Courageous leadership from our membership spearheaded the formation of the CMIC. Although extensively criticized and maligned – and at times rightly so – CPRO has become and will remain an important mechanism of control for the future. CPRO is an entity which was organized and is still controlled by physicians. It will be essential for the survival of a statewide IPA-HMO. Based on the feasibility study of the Ad Hoc CSMS IPA-HMO Committee, our professional consultants agree that the development of a statewide IPA-HMO owned and operated by CSMS member physicians is more than feasible!! The Council has accepted the report and is transmitting it to the House of Delegates for action on May 7, 1986. If this is approved, we will have in our possession the data and the ability to control our corporate destiny. I am unaware of any other State in the United States which will have achieved such a commanding governance through the control of these three basic enterprises.

Is there still a Holy Grail left in Medicine "abounding in the horns of plenty containing magic life-restoring cauldrons?" Each of us must still answer whether our own individual quest is still a dream, a phanthom apparition, or a ghost of the past. Whatever our plight, it appears inevitable that we can no longer survive alone. Our quest for the "mythical cup" must be consummated together. Hopefully, we will stand together and not perish alone!

William A. Whalen, M.D.
President

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Reflections on Medicine
Marketing or Humbug?

ROBERT U. MASSEY, M.D.

"It cannot be denied that in dealings with the public just a little touch of humbug is immensely effective, but it is not necessary.

"In a large city there were three eminent consultants of world-wide reputation; one was said to be a good physician but no humbug, the second was no physician and a great humbug, the third was a great physician and a great humbug. The first achieved the greatest success, professional and social, possibly not financial."[1]

In his counsels of perfection, Sir William Osler's manner was to deal gently with our fallible nature; he would have acknowledged, I am sure, that none of us, himself not excepted, is quite free of the virus of humbug. In some of the lesser works of the Hippocratic Corpus the writers were not above suggesting a little humbuggery:

"The dignity of a physician requires that he should look healthy, and as plump *(eusarkos)* as nature intended him to be; for the common crowd consider those who are not of this excellent bodily condition to be unable to take care of others."[2]

Being healthy and plump is hardly humbug; *looking* healthy to impress the customers and to improve the business "partakes of the nature" of humbuggery, but if the plump and healthy physician qualifies also as Osler's "great physician," what harm is that?

Comparing marketing with humbugging is at the very least uncharitable, at worst it is being careless with words. But certainly false or misleading advertising is humbug; it is also a marketing strategy which has never been entirely limited to shoddy enterprises.

I suppose that is why physicians feel uneasy when their hospital directors or HMO managers begin to talk about marketing, when their trustees from the world of business urge that new programs be designed for profit or to increase market share, always at the expense of their colleagues, and maybe their patients as well.

The very words feel wrong, and although the fine 18th century word "humbug" may not be the first to come to mind, "Madison Avenue" and "huckster" may be evoked, or at least the aroma that goes with them. More and more frequently I have heard doctors say that this isn't the profession they came into. Medical students with their ideals more shiney and new withdraw with a kind of revulsion, blaming us for selling out to mammon.

Good marketing is only good education, our business masters tell us, simply another fine service to our clients; they almost persuade, but the words are all wrong and the perceived intent feels unpleasant; he who would sup with the devil must have a long spoon, to paraphrase Chaucer; perhaps it would be better to decline the invitation in the first place.

We should take heart and remind ourselves that we have tried all this before. Writing over sixty years ago, Abraham Flexner noted:

"The medical profession now knows better; but large sections of the people have not yet unlearned the bad lesson they were then taught; so the medical sectarians employing a technique compounded of illusive promises, bragging and advertising, operate profitably on a scale that would have amazed, perhaps even shocked, the regular profession in the heyday of proprietary medical education."[3]

The idealism of Osler, and of the Hippocratic writers at their best, is a heartier perennial, thank goodness, in our profession than humbuggery. If we cannot make it bloom again in our time, those who follow us will; our students would agree with Osler, "Not that we all live up to the highest ideals, far from it—we are only men. But we have ideals, which mean much, and they are realizable, which means more."[4]

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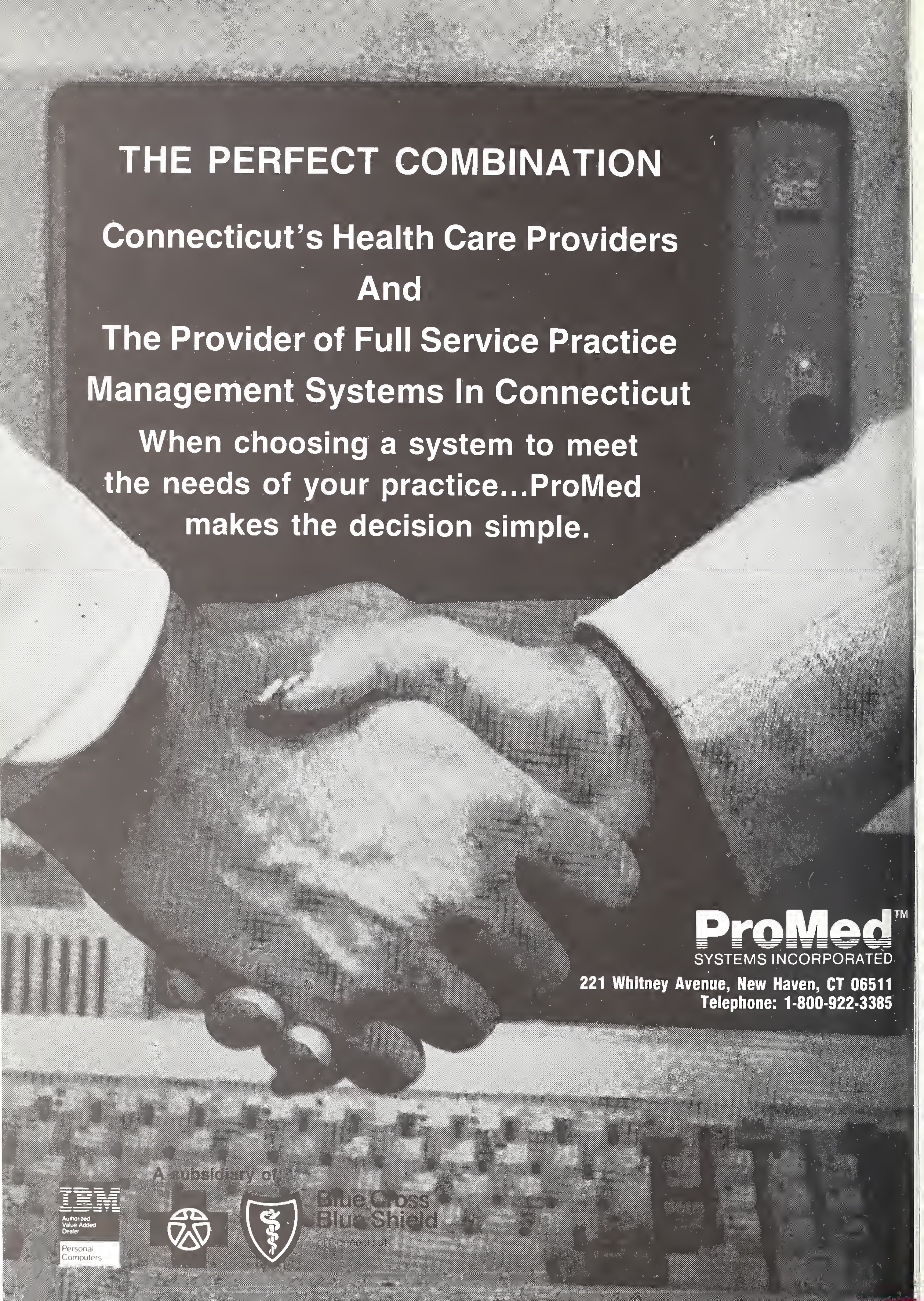

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Surrogate Decisionmaking for the Incompetent Patient: Connecticut Perspectives

JOSEPH M. HEALEY, J.D.

Following my recent columns dealing with various strategies to permit currently competent patients to exercise control over decisions which might occur at a future time when those patients would be incompetent, I received a letter[1] from my friend and colleague, Dr. Robert Harkins, a physician-attorney, expressing concern that one of my alternatives (durable power of attorney) was incorrect, that a second (the naming of one's own conservator for future incapacity) had serious limitations, and that a third (application for voluntary representation) had not been offered. The issues raised by Dr. Harkins are important and will serve as the focus of this month's column.

Dr. Harkins correctly points out that the primary focus of the sections of Connecticut General Statutes dealing with the power of attorney[2] is on business decisions rather than personal decisions such as health care. However, I think he overstates his case. An examination of the statutory short form of power of attorney[3] explicitly discusses areas such as real estate transactions, chattel and goods transactions, banking transactions and the like. It is clear, however, that in the Short Form itself and in the language of subsequent sections[4] that the person creating the power of attorney is entitled to supplement the specifically listed powers so long as they are not inconsistent with the other provisions of the statutory short form power of attorney. The use of this language to support the use of a power of attorney in health care decisions has not been reviewed by our Supreme Court. My own view is that such an interpretation is consistent with the overall goals of the sections dealing with power of attorney and is consistent with the evolving experience of other states. Clarification could occur either through a definitive examination of this language by the Connecticut Supreme Court or by legislative action, such as the adoption of a specific statute regulating durable power of attorney for health care purposes such as that enacted in California.

Dr. Harkins correctly points out that the section of Connecticut General Statutes dealing with advanced designation of conservator[5] does not create a surrogate but merely identifies the person whom the subject would like to be designated conservator by the probate court. The advantage of this strategy, however, rests in extending to the currently competent patient, the authority to choose the person to be a surrogate (if needed) and to communicate any instructions about decisions which might be necessary. This allows the patient who is afraid of the powerlessness which accompanies incompetence to retain some degree of control. If the patient were to become incompetent, it would be the responsibility of the probate court to confirm such a conclusion and to appoint a surrogate. The wishes of the patient would be given great weight in determining the fitness of a candidate to serve as conservator. I view these procedures as strengths rather than weaknesses and their use to be valuable for the patient.

Finally, Dr. Harkins supports the use of the application for voluntary representation[6] as a vehicle through which a competent person may petition the court for the appointment of a conservator without making a finding that the patient is incapable. This conservator would have authority from that moment onward. This process appears to be useful in those cases when a patient is gradually slipping from competence to incompetence and there is need to clarify who is the responsible decision-maker. My own problem with this strategy is the uncertain legal status of the applicant after the appointment of a conservator has been approved. Under traditional principles, the appointment of a conservator usually signals the transfer of legal authority from the patient to the conservator. As was true of the power of attorney, this language has not been interpreted definitely by our state Supreme Court and the uncertainty will persist until judicial or legislative clarification occurs.

It is not surprising that there remain controversies about advantages and disadvantages of using the various strategies to protect patient rights when incompetence occurs or is likely to occur. One hopes that the additional attention focussed on these issues will lead to further clarification.

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6. Connecticut General Statutes Sec 45-70e.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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The Journal of the Connecticut State Medical Society
160 St. Ronan Street, New Haven, CT 06511

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Editorial

Who's in Charge Here?

As many know, Dr. Fred Fabro stepped down as Editor of *Connecticut Medicine* several months ago. The words "stepped down" are quite appropriate since he had ascended to great heights with the publication of this Journal. The accolades given him for his achievements in this fine job of Editor are noted in several places in our Council Minutes, as well as tributes to his honor which will be made at the annual meeting of our House of Delegates. The following is written so that our membership will be assured as to the continued operations of your Journal in this transition period and certainly in the forthcoming years.

As a medical student in Philadelphia 40 years ago, I was always anxious to read the doings of our State Society and of the scientific matters presented in *Connecticut Medicine.* As a student, I thought that it was very nice to receive such a journal through the courtesy of our State Society. Although Connecticut was my home state, I did not know definitely that I would practice back here again, but, in any case, it was always recieved with pleasure and anticipation. As another measure of the esteem with which our Journal is held, a survey was taken a few years ago as to the readership of this Journal. At that time, I was chosen to investigate (as chairman of the committee delegated to do this job), how acceptable our Journal is to the members of the Connecticut State Medical Society. In the final outcome, we were pleased to learn that it ranked quite highly, even compared to several other prestigious journals. Some statistically-minded person has ventured figures as to the available time that the average physician has to read the many journals, scientific literature, etc., that come across his desk in the course of the week. It has been stated that if a doctor spent all of his time reading such journals, there would be no time whatever for practicing medicine (to say nothing of trying to find time for any other pursuits of life!). At this time, I wish to reassure the membership that the Editorial Board fully understands the great competition that *Connecticut Medicine* has with the many other journals and leisure reading that our readers partake of on a regular basis.

As a member of the Editorial Board, I have enjoyed working with the other members and especially with Dr. Fabro over the last several years. I was often assigned duties to review scientific articles in the field of Ob-Gyn and related topics. Being in solo practice in these busy times, I did not actively seek this interim job as Editor, but must immediately state that I have enjoyed every bit of it for this short period of time.

We now come to the matter of the Search Committee, which has been seeking a permanent Editor for our Journal. Time was given for the Search Committee to adequately interview prospective applicants for this position, and I am sure that the fruits of their efforts will be forthcoming quite shortly. At a recent Editorial Board meeting, further improving the interest of our Journal was discussed. It will be a definite goal of the Editorial Board and any new editor to help our scientific writers within our state to come forth with scientific articles of interest to the membership. This last sentence is meant as an invitation to our many physicians who have something to say scientifically but, for whatever reasons, demur. I heartily encourage you to get such scientific findings and thoughts into the best possible form for submission and consideration for publication in *Connecticut Medicine.* Here you will find many reasonable people who will try to help you with such an endeavor. I am sure that the philosophy of the new editorship will include a proper balance of such scientific articles from our "home-grown" physicians; medical-political issues of interest, scientific articles from outside our own area, and the many archival functions of our Society which need reporting to the membership at large. Also, we would like to hear further "Letters to the Editor" and any other suggestions that

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you might wish to make verbally or in writing to us regarding the content of your Journal. I am sure that I can speak for any new Editor by saying this.

Finally, I cannot begin to give enough thanks to the many, many people who have helped me during this transition period. At the risk of sounding like an Oscar recipient, I would have to mention the great help that I have had from the staff and Editorial Board, and in particular from Mrs. Vivian Feriola, in getting together this Journal on time and in what I believe to be in very good condition. The nomination of the new Editor will be made quite soon. I plan to fully support all efforts of the new Editor, and I am sure that the Editorial Board and the Society members at large will join me in this. Thank you for this experience.

Stewart J. Petrie, M.D.,

Editor Pro tem

Letter to the Editor

THE ROLE OF THE LIVING WILL

To the Editor: Professor Healey's trilogy on PA 85-606 "An Act Concerning Death Dignity" properly tells us that the Connecticut Legislature has done nothing in modern times to facilitate assurances to a person that his treatment wishes will be honored should he become incompetent. In his Part I Article, Professor Healey listed currently available means by which a Connecticut resident could create a surrogate who would have authority to make treatment decisions should the subject lose competency.

I believe that one of his alternatives is incorrect, that a second has serious limitations; and that a third was not offered.

CGS§45-69o "Durable Power of Attorney" does not create a surrogate who can make health care decisions for a subject; surrogate authorities from this section are limited to business decisions and do not include decisions about personal matters such as health care treatments. CGS§ 45-70 "Naming of Own Conservator for Future Incapacity" does not create any surrogate, but merely states whom the subject would desire to have as conservator should probate court have occasion to declare the subject incompetent and in need of a conservator.

A statute currently on the books which permits creation of a surrogate who can make health care decisions for the subject should the subject lose competency is CGS§ 45-70e "Application for Voluntary Representation." Under this statute a competent person may petition the probate court to have a particular person appointed as his conservator (of estate and/or person). The probate court holds a hearing at which the judge may talk with the subject/petitioner and with the potential surrogate/conservator. The Court may then appoint the surrogate/conservator who has authorities from that moment, and those authorities persist even should subject lose competency.

California has seen clear to legislate a durable power of attorney for health care purposes, the advantage over voluntary conservatorship being that the durable power of attorney for health care purposes is more easily and less expensively created because no probate court appearances are invoked.

Should the Connecticut Legislature recognize that surrogate decision-making is an exceedingly common phenomenon, and that formal appointment of surrogates once competency has been lost can be ponderous, it might elect to legislate a durable power of attorney for health care purposes. Until it does, Connecticut residents who desire some equanimity about health care treatment decisions in the future might gain it via CSG§ 45-70e "Application for Voluntary Representation."

Robert W. Harkins, M.D., JD

Middlebury, CT

Changes in Premature Mortality—
—United States, 1983-1984

Premature mortality in the United States, as measured by years of potential life lost before age 65 years (YPLL), increased from 1983 to 1984 for the first time since 1980. Total YPLL from all causes of death increased from 11,712,000 in 1983 to 11,761,000 in 1984—a 0.4% increase. The rate of YPLL per 1,000 persons younger than 65 years of age, however, decreased by 0.4% from the 1983 level to 56.5/1,000 persons. An increase of 1.5 million persons younger than 65 years of age accounts for this descrepancy.

The relative rankings of the leading causes of YPLL did not change substantially from 1983 to 1984. The only change was cerebrovascular diseases replacing chronic liver diseases as the eighth leading cause of YPLL. Unintentional injuries (accidents) continue to head the list, accounting for 20% of the total YPLL, followed by malignant neoplasms (15%), diseases of the heart (13%), and suicides/homicides (11%).

The rate of YPLL per 1,000 persons increased for eight of the 12 leading causes of death. The largest proportionate increase in the rate of YPLL was recorded for cerebrovascular diseases, which was up 13.1%. Increases in YPLL rates were also noted for prematurity, up 3.3%; sudden infant death syndrome, up 2.7%; pneumonia and influenza, up 2.6%; and diabetes mellitus, up 1.8%. In contrast, the rate of YPLL for chronic liver diseases and cirrhosis decreased by 7.4%; diseases of the heart declined 3.6%; chronic obstructive pulmonary diseases and allied conditions were down 3.3%; and malignant neoplasms, down 1.3%.

CDC Editorial Note: With this issue, the CDC announces a change in the method of calculation of YPLL to include causes of mortality in the first year of life. The relatively high age-specific death rate of these infants, combined with the years of life remaining before age 65 years, adds two new causes to the list of leading causes of YPLL—sudden infant death syndrome (ICD code 798) and deaths attributable to prematurity, including neonatal respiratory distress syndrome (ICD code 769) and disorders relating to short gestation and unspecified low birthweight (ICD code 765).

The inclusion of deaths in the first year of life does not account for the increase in total YPLL from 1983 to 1984. Although total YPLL decreased each year from 1980 to 1984, the slight increase in 1984 is present when YPLL is calculated by either the birth-to-65-years-of-age or the 1- to 65-years-of-age method. The rate of YPLL per 1,000 persons, however, has decreased each year since at least 1979 using both methods of calculation and now stands 12.3% below the 1979 level when measured from 1 year of age to 65 years of age, and 14.1% when measured from birth to 65 years of age.

Considerable variability continues to be demonstrated in the year-to-year comparison of YPLL rate because of specific causes of death. The rate of YPLL attributable to cerebrovascular diseases, for example, increased by 13.1% in 1984, reversing the 12.4% decline in the previous year. In contrast, the YPLL rate for unintentional injuries, which has consistently decreased from 1979 until 1984, increased by 0.4% in 1984, but remains 22.5% below the 1979 level.

—Reported by Epidemiologic Studies Br, Div of Surveillance and Epidemiologic Studies, Epidemiology Program Office, CDC.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511 Telephone 865-0587

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COUNCIL MEETING

March 26, 1986

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle were: Drs. Ahamed, Ahrens, Beck, Canzonetti, Czarsty, Freedman, James, Kamens, McDonnell, Orphanos, Petrie, Ragusa, Robbins, Rose, Sadowski, Scheer, Schwartz, Seide, Sullivan, Jr., Sweet, Waldron, Welch, Zanker and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Ms. Marcus, Mr. Sullivan, Mr. Tomat (FCMA) and Mr. Fiorentino (HCMA).

Absent were: Drs. Abbot, Bobruff, Bonner, Dardick, Eslami, Friedberg, Kaess, Reyelt, Jr., Villa and Whalen, Jr.

Report of the President

Dr. Whalen was unable to be present at this meeting and submitted a written report covering the following items:

IPA/HMO—It is expected that the final report will be ready in time for submission to the House of Delegates and it is expected that consultants will be present at the meeting to answer questions.

Legislation—Dr. Whalen reported that he attended all the legislative meetings and was pleased with the progress of the CSMS legislative program.

AMA Award—Reported on a letter received from the AMA recognizing that the CSMS, for four consecutive years, has surpassed its previous year record of AMA members.

Following discussion of different aspects of the report, it was VOTED that CSMS Staff research the official accepted policies of CSMS on the important issues of the day. A sampling extracted from the AMA publication on policies was submitted for reference.

Committee on Physician Health

Dr. Gerald Flamm, Chairman of the subject committee, joined the Council to discuss the activities of his committee. After discussion, the following actions were taken:

It was VOTED to approve a recommendation "that the CSMS Council establish a program protocol governing participation of established medical organizations in the implementation of Public Act 84-148 and to provide an approved resource for physicians in counties lacking programs at present."

Update on Nursing Home Visits

1. *HCFA Meeting*

> Dr. Joseph Czarsty reported on his trip with Dr. Andrew Weinberg and Shelley Marcus to the HCFA regional office in Boston on February 19. Although they received a cordial reception, after an hour and a half of discussion, the request from CSMS to approve monthly nursing home visits, as medically necessary, was denied by HCFA as contrary to regulations.

It was VOTED that CSMS staff conduct a survey of physician members of CSMS to determine the number involved in retrospective audits by CIGNA/HCFA for nursing home visits. The questionnaire should include such questions as whether they make nursing home visits? Are they being audited? Are patients being harmed by the restrictions put on visitations? The questionnaire is to be confidential and a cover letter should explain why the survey is being undertaken.

2. *AMA Action on Nursing Home Visitation and Regulations*

> Dr. Jerome Freedman submitted the following report of the actions taken by the AMA Council on Medical Services, and the Texas Delegation to the AMA:

Nursing Home Visitation and Regulations

The AMA Council on Medical Services recently recommended the following AMA positions (Report F I-85):

a. The AMA should seek changes in the "Conditions of Participation for Skilled Nursing Facilities" so that a little flexibility in physician visitation requirements might result. Specifically a five day leeway was mentioned.

b. The AMA should seek more flexibility in the Medicare regulations concerned with drug and treatment orders in SNF's.

c. The AMA should encourage state medical societies to work with state legislatures and regulatory bodies to modify state regulations to match the federal ones.

The Council reached these conclusions after review of the federal requirements, discussions with the Wisconsin and New York State Medical Societies which sponsored resolutions that began the Council's activity, and discussions with Health Care Financing Administration representatives.

Punishment of Physicians by the Medicare Program

When the Federal Department of Health & Human Services applies monetary penalties and/or suspension from the Medicare Program to a physician, the physician's legal remedies are limited. As the regulations are written now, all the physicians can do apparently is to ask the U.S. Court of Appeals to review the record as a whole. Judicial review is restricted to whether the facts alleged appear to be backed by substantial evidence in the record as a whole.

Since there is no opportunity for a trial by jury, the Texas Delegation to the AMA in R 93 (I-85) asked the AMA to attempt to have Congress amend the Social Security Act to permit a trial *de novo*, when penalties exceed $10,000 and/or when a suspension from the Medicare Program is ordered.

Following discussion, it was VOTED that these actions be transmitted to the House of Delegates for consideration.

Committee on Statewide Medical Planning

Following discussion concerning the General Assembly's consideration of mandating Medicare Assignment, the following actions were taken on the recommendations of the subject committee:

a. It was VOTED to approve of the development of a Statewide Senior Medical Courtesy Card Program, through the county medical associations, patterned after those of Hartford and Fairfield counties, and to encourage counties that are not operating under this plan to make every effort to implement such a program.

b. It was VOTED to table the recommendation that the Committee on Hospitals be requested to study the medical and social implications of early hospital discharge of elderly patients, since this study has already been undertaken.

c. It was VOTED to approve the recommendation that the CSMS Council urge Governor O'Neill to activate and fund the Professional Advisory Committee to study the medical effectiveness of the Prospective Payment Program.

Report of Subcommittee on Preliminary Study of Nominations

With a few amendments, it was VOTED to approve the report of the Subcommittee, and to transmit the complete slate of nominees to the House of Delegates for election with Council recommendation for approval.

Nominations of Directors of CMMI

According to the CMMI Bylaws, the Council should nominate and select directors for election by the House of Delegates of CSMS and transmit nominees to CMMI in time for their annual meeting, which usually follows the CSMS meeting. It was VOTED to approve the following slate of nominees: Jerome K. Freedman, M.D., W. Raymond James, M.D., Sultan Ahamed, M.D., Timothy B. Norbeck, Daniel W. Doctor, M.D., Kevin D. Dowling, M.D., Mehdi S. Eslami, M.D., James P. Orphanos, M.D., Joseph S. Sadowski, M.D.

AMA Judicial Council Opinion Re:

Ethics of Withholding Life Prolonging Medical Equipment

The Council referred consideration of a recent AMA Judicial Council opinion concerning withholding life prolonging equipment to the Committee on Ethical and Judicial Affairs. The opinion determined that it would be ethical for physicians to withhold "all means of life prolonging medical treatment," including food and water, from patients in irreversible comas.

It was also VOTED to approve the CSMS pamphlet entitled "Dignity in Life and Death."

CSMS-Sponsored Symposium

A request was received from Andrew D. Weinberg, M.D., to sponsor a statewide symposium concerning the changing environment of geriatric care. It was noted that $3,000 in funding support had been secured for the symposium from the Upjohn Educational Division. Following discussion, it was VOTED to sponsor the symposium with the proviso that a budget be submitted to the Society and that CSMS will not assume any liability for any expenses that have not had previous approval.

Life Members

The Council approved the following list of Life Members effective 1/1/86:

Name	Town
G. Lawrence Austin, Jr.	Unionville
Charlotte R. Brown	New Canaan
Andrew J. Canzonetti	New Britian
Nicholas T. Phillips	Norwich
Marjorie A. Purnell	Rockville
Nicholas P. Spinelli	Devon
John L. Sullivan	Bridgeport

Legislation

Shelley Marcus enlarged upon the minutes of the Committee on Legislation and reported that House Bill 6134, An Act Concerning Tort Reform would receive a public hearing before the Judiciary Committee on March 31, 1986. It was noted that the proposal contains all elements of the CSMS tort reform package, except a cap on pain and suffering.

Dr. Petrie reported on his attendance at a meeting of the CSMS Committee on Legislation and reported that the legislative aims of the Society were being followed very carefully and that physicians should write to their legislators in support of tort reform, which is the major issue at this time.

Dr. John Sullivan inquired about CSMS activity concerning a bill that would mandate immediate admission of psychiatric patients. Ms. Marcus reported that the Psychiatric Association has its own lobbyists and although we have not been directly involved, the bill is being tracked. Following discussion it was VOTED to approve the following motion:

> "The Council of the State Medical Society strongly supports the Senate Bill that requires the Commissioner of Mental Health to accept all committed patients to state hospitals immediately. Those committed patients are a danger to themselves and others and are unable to care for themselves, as is indicated in the Senate Bill that has already been passed by the Public Health Committee and is currently before the Appropriations Committee."

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on March 26, 1986. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

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FACT SHEET ABOUT CONNECTICUT PHYSICIANS

The following facts have been collected from non-medical sources by the Connecticut State Medical Society's legislative consultants, Sullivan & LeShane of Hartford, Connecticut.

They illustrate the problems that exist in professional liability matters.

HOW MANY LICENSED PHYSICIANS RESIDE IN CONNECTICUT?

As of January 1, 1986, there were 8,032 licensed physicians residing in Connecticut.

WHAT ARE PHYSICIAN MEDICAL MALPRACTICE PREMIUMS IN CONNECTICUT?

According to Premiums quoted by the Connecticut Medical Insurance Company, the medical malpractice premiums in Connecticut for 1984 and 1985 were:

	'84	'85
Internists	7,231	9,636
Orthopedic Surgeons	36,618	51,899
Obstetricians	36,618	51,899

HAS THE FREQUENCY OF MEDICAL MALPRACTICE CLAIMS RISEN IN CONNECTICUT?

Yes. The Judicial Department reports that:
In FY 78-79, there were 241 claims filed in Ct's courts.
In FY 84-85, there were 534 claims filed in Ct's courts.

HAS THE FREQUENCY OF MEDICAL MALPRACTICE CLAIMS RISEN NATIONWIDE?

Yes. Nationwide claims have risen from 17,238 in 1978 to over 30,000 in 1981.
In 1978, there were 12.17 cases per 100 physicians.
In 1984, there were 24.8 cases per 100 physicians.

NATIONWIDE, WHAT ARE THE MOST FREQUENTLY MADE CLAIMS AND AVERAGE PAYMENT FOR EACH?

According to a 1979-83 statistics from the St. Paul Companies, the following five claims are the most frequently made. Approximately two-thirds of all claims are closed without payment.

1. Surgery:	post operative complication
2. Improper Treatment:	birth related
3. Surgery:	inadvertent act
4. Failure to Diagnose:	cancer
5. Surgery:	inappropriate procedure

HAS THE AMOUNT OF MALPRACTICE AWARDS AND SETTLEMENTS RISEN NATIONWIDE?

Yes. Figures reported by Jury Verdict Research rose at an average annual rate of 24.7% during the period 1979-83.
The average Jury awards grew more than five fold from $166,165 in 1974, to $888,285 in 1983.

HAS THE NUMBER OF MILLION DOLLAR JURY VERDICTS GROWN?

Yes. According to Jury Verdict Research, there were 1,642 million dollar verdicts by 1984. In 1983, juries awarded 360 million dollar or more verdicts, the largest number on record for a single year. Million dollar verdicts are being rendered at a rate of more than 6 per week.

HOW MANY MILLION DOLLAR VERDICTS HAVE THERE BEEN IN MEDICAL MALPRACTICE CASES?

According to Jury Verdict Research, there have been 296 million dollar or more medical malpractice awards through 1984. Since 1977, at least 10 verdicts of one million dollars or more have been rendered in medical malpractice suits annually.

HAS MEDICAL PROFESSIONAL LIABILITY RAISED THE COST OF PHYSICIAN'S SERVICES?

Yes. According to a 1985 Center for Health Policy Research study, the total effect of medical professional liability has been to raise the cost of physician's services in 1984 by $2 billion.

HAVE CONNECTICUT PHYSICIANS LIMITED THEIR PRACTICES IN ORDER TO LOWER THEIR MALPRACTICE INSURANCE RATES?

Yes. In a survey conducted in August '85, 33% of the CT. physicians responding have limited or reduced the scope of their practices in order to lower their malpractice insurance rates.

ARE CONNECTICUT PHYSICIANS PRACTICING DEFENSIVE MEDICINE DUE TO THE INCREASED FREQUENCY OF LITIGATION?

Yes. 77% order more diagnostic work than would otherwise have satisfied their clinical judgment.
81% refer patients they would have previously handled themselves for additional consultation.

IF TORT REFORMS WERE ADOPTED, WOULD THERE BE A MEDICAL LIABILITY SAVINGS?

Yes. According to an '85 acturial study, the following tort reforms would account for an initial savings of:

Tort Reform	Savings
Periodic Payments	6%
Collateral Source Offset	8%
Limitation of Non-Economic Damages	12%
Contingency Fee Limitation	9%
Total	28%

WHAT EFFECT DOES LIMITS ON ATTORNEY'S CONTINGENT FEES HAVE?

According to a Rand Corporation Study, limits on attorneys fees have:

- cut average settlements by 9%.
- raised the number of cases dropped without payment from 43% to 48%.
- reduced the percentage of cases going to verdict from 6.1% to 4.6%.

NATIONALLY, DOES THE PUBLIC FAVOR LIMITING AWARDS?

Yes. According to a July '85 poll conducted by Kane, Parsons, Inc. and V. Lance Torrance and Associates, 56% of the public nationally favors limiting awards, 31% are opposed, and 13% are undecided.

DO CT. CITIZENS BELIEVE THAT THE COLLATERAL SOURCE RULE SHOULD BE EXTENDED TO PREVENT DUPLICATE PAYMENTS?

Yes. According to the 1985 Becker Institute Poll, 72% responded that the court award should be reduced by the amount already paid from an insurance policy.

DO CT. CITIZENS APPROVE OF CAPS ON NON-ECONOMIC DAMAGES?

Yes. When posed the question, "in Connecticut, it has been proposed that after all economic damages have been paid, the law should place a top limit of $250,000 on the amount that can be awarded to pay for non-economic damages," 66% approved placing this top limit on non-economic damages according to the Becker Institute Poll.

Earnings Survey Shows Female MDs Gaining

Female physicians may be cutting into the earnings lead their male counterparts have traditionally held, an AMA study suggests.

Between 1982 and 1984, female physicians' inflation-adjusted income rose 17.8% annually, compared with 5.4% for male physicians, according to a report from the AMA Socioeconomic Monitoring System. More important, female physicians' income growth generally outdistanced men's in the area where it has lagged behind the most—among doctors with five or more years of experience.

The SMS survey, conducted during 1984 and 1985, shows that inflation-adjusted income rose the most for physicians with fewer than five years of experience—the period when doctors' income historically has risen the fastest. For female physicians in this experience category, inflation-adjusted income rose at a 24.8% annual rate, compared with 22.3% of men. The report notes that this experience category comprises 46.4% of female physicians and 23% of men.

Among physicians with five to nine years of experience, income rose 11.1% annually for women but fell 0.5% for men. For 10 to 19 years and 20 to 29 years of experience, female physicians' income rose 11.6% and 20.9% annually, but among women in practice for 30 years or longer, income dropped an average of 11%.

By comparison, male physicians' earnings rose at a 3.5% annual rate for the 10- to 19-year category, fell 0.5% in the 20- to 29-year group, and rose 4% for those in practice 30 years or more.

An SMS analyst noted that because of small sample size, the figures for female physicians are statistically different from zero only for those with four or fewer years and 10 to 19 years of experience. Nonetheless, the figures indicate women are closing the income gap, he said. However, the survey also shows that female physicians in all experience categories still earn less than men do, he added.

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The Health Care System in the Mid-1990's

The Study

This report presents the results of a study conducted by Arthur D. Little, Inc. for the Health Insurance Association of America. The purpose was to provide a description of the health care system as it is likely to appear in the mid-1990s, based upon the informed judgment of experts inside and outside the system.

The study sought to identify the most probable characteristics of the health system, the major areas where experts feel uncertain or disagree, and some of the important causal factors that influence the system.

One component of the study approach was to identify basic forces that affect the health care system but are independent of decisions made by health care policy makers or providers, between the present time and 1995. Assumptions about these forces are taken as "givens" in the health system picture:

- A U.S. population growth of about 18 percent between the years 1980 and 2000.
- Continued growth in the proportion of the population that is aged 65 and over and, especially, in the population aged 75 and over.
- Continued improvement in the financial status of many of the aged, with many others remaining below the poverty level.
- Continued growth in the supply of physicians, resulting in a marked surplus by 1990 and an even larger surplus by 2000.
- A continued oversupply of hospital beds, reflecting diminishing need and the difficulty of dismantling capacity already in place.
- Economic growth, inflation rates, and employment rates falling between existing "high" and "low" projections, without any major disruption such as a large-scale war or other comparable development.

A series of personal interviews was conducted with 40 nationally recognized leaders in health care, representing the academic world, providers, business, labor, and insurers. These interviews constituted the heart of the study and were the basis for an initial draft of a health care system description for the mid-1990s.

The description was tested and refined through a more tightly structured telephone survey, which reached an additional 85 health care experts. Finally, three small "focus" groups of health care experts were convened to sort the mass of information received into the basic ideas highlighted in this summary.

It is important to call attention to what the report is and is not. Except for projections concerning driving forces and study assumptions, the report is not a set of predictions based on analysis of data. Instead, it is an attempt to present the collective views of knowledgeable persons as to where the health care system is headed and by what pathways. It is intended for use not as a factual reference but as a guide for anticipating and interpreting developments as the health care system evolves.

Findings: Profile of the Health Care System in 1995

1. There will be a change in the way health care is perceived by participants in the health system—providers, consumers, payors, and policy makers. This can be characterized as a shift away from the traditional view of health care as a social good that is exempt from market forces, and toward a view that it is an economic good subject to the influence of supply, demand, and price.

2. Government and business purchasers of health care will intensify efforts to contain costs, which will dominate the health care agenda.

- The federal government, continuing its retreat from guaranteeing health care, will concentrate on limiting its financial outlays. This retrenchment represents a shift away from the concept that government should ensure equal access to health care for all.
- The government will resist participating in a regulatory structure that affects the overall health system because it believes it can spend less on health care services by "going it alone."
- For a time, the government will continue to refine the concept of DRG-based reimbursement as a major tool for cost containment. Eventually, however, the complexity of DRGs will probably lead to their replacement by a wholly or primarily capitation-based reimbursement system.
- Areas of uncertainty are: (1) how far DRGs will be developed before they are replaced; (2) to what extent Medicare will seek to shift responsibility to the private sector, through increased cost-sharing, means testing, or vouchers; and (3) to what extent Medicare will take the lead in rationing the use of costly "heroic procedures" for the terminally ill.
- More states will adopt prepaid systems or "primary care networks" for Medicaid, in which access to specialist and inpatient services is controlled by a "gatekeeper" primary care physician. These systems

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represent the abandonment of a long-held ideal that the poor should have the same choice of health care provider as the affluent.

- Employers will continue to be more demanding about health care cost containment. Employers will continue to adopt cost containment approaches, resulting in a demand for more diverse and "customized" insurance and insurance-related services. They will continue to be involved in collective planning, negotiating and lobbying through health care coalitions and national organizations.
- The American public will not accept rationing of health services on the British model, involving denial of beneficial but expensive care to persons who do not meet qualifying criteria.

3. The health system in 1995 will be highly competitive and, to some degree, regulated. Although competition and regulation have often been considered as opposing strategies, any realistic picture of the future health system must include both.

- Because of system over-capacity, competition is inevitable with or without regulation.
- Competition probably will be aimed less at the consumer and more at the employer, union, or other surrogate purchaser. Emphasis will shift somewhat away from consumer choice through cost-sharing and multiple-option plans, and toward external controls on utilization.
- The outlook for a cap on the tax-exempt portion of health benefits is uncertain. Such a measure would increase interest in consumer choice strategies.
- Neither a centralized, heavily regulated health system nor a totally deregulated system appears likely to become established in the near future. Centralized regulation is believed to be too expensive, inflexible, cumbersome to administer, and antithetical to contemporary values. Total deregulation would lead to inequities so glaring that the public would demand re-introduction of regulation.

4. Regulation is most likely at the state level, varying from state to state. This is an important area of uncertainty.

- The outlook for state all-payor rate-control systems is uncertain because Medicare will not participate unless these systems are perceived to result in lower Medicare costs than can be achieved by "going it alone." The extent to which rate controls are adopted will affect the nature and intensity of health care competition. In the absence of such controls, cost shifting by providers from Medicare to private third-party payors will intensify private sector cost-containment activities and price competition. If rate controls exist, cost shifting will be reduced and prices will become more uniform. Competition will be less intense, based more on product than on price.
- Also uncertain are prospects for other forms of regulation with potential cost containing effects, such as revitalized certificate-of-need programs or controls on malpractice litigation.

5. Evaluation of cost containment strategies will be aided by a major improvement in the availability of information on health care utilization, cost, and quality.

- The quality of employee/beneficiary utilization data is expected to improve rapidly, with employers, insurers, and government payors concerned with monitoring costs, and providers concerned with justifying them.
- Research on health care outcomes will improve our understanding of the relationship between quality and costs, thus enabling regulators and private sector purchasers to influence the health system toward greater cost-effectiveness.

6. Consumers will increasingly accept responsibility for their own health care.

- Consumers with good health habits will be less willing to subsidize care for policyholders whose lifestyles make them higher health risks. This will encourage insurers to design benefits that reward good health habits and penalize poor ones.
- Consumers will also increasingly accept the idea that regardless of the reasons for use of the health system, the greatest users should pay the largest share of costs.
- Consumers will become more interested in efficient management of the system and willing to relinquish some of their autonomy for more cost-effective care.

7. Demographic change, cost containment, and evolving consumer attitudes will change the mix and delivery of services.

- There will be more health care services for the aged.
- By the mid-1990s or earlier, there will be intense public pressure for protection against the costs of long-term care.
- A variety of specialty services will emerge, reflecting physician competition for market niches.
- The shift of care from in-patient to ambulatory settings will accelerate.
- More health care will be delivered in managed systems, including HMOs, preferred provider networks, and traditional fee-for-service care, with tighter controls on utilization. Population mobility and increased physician specialization have rendered obsolete the ideal of a long-term relationship with a family physician who provides most of the care needed. Consumers need guidance in making health care decisions. They will increasingly prefer systems

in which physicians are subject to external monitoring and control.

- By the mid-1990s, growth in extrepreneurial, free standing ambulatory care services will have tapered off and many will have been absorbed by large health care systems.

8. Regardless of the extent of health systems regulation, a "safety net" will provide a limited guarantee of access to care.

- The public will not permanently accept a system in which people cannot get care because of inability to pay.
- The safety net will incorporate restrictions on provider choice.
- The form that the safety net will take and the role to be played by insurers are uncertain and will probably vary from state to state. Possibilities include insurance risk pools, tax revenues allocated to public facilities, uncompensated care allocations to hospitals, and expansion of Medicaid programs.

9. A "tiered" system of care will be recognized and accepted.

- This nation is relinquishing the ideal of full access to "mainstream" health care for all.
- Probably we will see a multi-tiered system, with different options available to the categorically eligible poor, the unemployed or medically indigent, those with group insurance, and the affluent.

10. Cost containment and overcapacity will combine to change the way hospitals function.

- Hospitals will integrate into corporate structures—investor-owned and voluntary—which provide management and capital resources required to compete effectively.
- Price competition will make it more difficult for teaching hospitals to support their teaching activities, maintain costly standby services and continue to provide their historical share of uncompensated care. To maintain their patient census and improve their financial status, many of these hospitals will form relationships with community hospitals.
- Investor-owned chains will account for a larger share of hospital beds, but are not predicted to dominate the industry.
- Hospitals will diversify, adopting a variety of new services to provide sources of income, maintain their share of the hospital market, and meet competition from physician groups and entrepreneurs.
- Hospitals will combine a variety of services with insurance and/or prepaid programs to offer totally integrated health care systems.

11. The growing surplus of physicians amid pressure for cost containment will change the nature of physician practice.

- Physician income will grow more slowly.
- Medical practice will become more standardized.
- More physicians—and a larger proportion of women physicians—will practice in salaried settings.
- Physicians in private practice will join efficiently managed groups. Solo practice will virtually cease to exist.
- Use of mid-level practitioners will be inhibited by the increase in physician supply.

12. HMOs and other capitation arrangements will experience explosive growth.

- By 1995, HMO penetration is expected to have increased from the present six percent of the population to 25 or 30 percent or more.
- Major areas of growth will include investor-owned HMOs, HMO networks or chains providing nationwide coverage, and "competitive medical plans" servicing Medicare beneficiaries.

13. Negotiated provider contracts will be based on services and management efficiency rather than on price discounts. Preferred provider organizations offering discounts to employers probably will not be successful over the long term.

14. Cost increases will taper off.

- Estimates of health care spending as a share of gross national product cluster around 12 percent but range widely.
- Not enough is known about the effectiveness of cost-containment strategies to permit more exact projections.
- Cost containment could be greatly affected by changes in public attitude resulting from evidence of a positive or negative relationship between cost containment and quality of care.

Conclusion

Government and corporate concerns about health care costs, changing demographics and excess supply in the health care delivery system are driving forces for change in the provision and financing of health care over the next decade. Fundamental shifts in the role of government, erosion of public support for access to a single system of health care for all, and growing acceptance of the view that those who follow unhealthy lifestyles or are high utilizers of health care resources should bear a greater share of the costs of care will fuel the forces for change—accelerating and broadening the impact.

The trend toward managed health care, integration of hospitals and physician groups into larger, more powerful and more business oriented units, and deemphasis of inpatient care, are some of the changes anticipated. While market forces will reshape the system, changing the nature, location, and structure of health services, competitive ferment will be tempered by regulation if access to care is significantly reduced, and quality of care perceptibly diminished.

IN MEMORIAM

CLASON, FREEMAN P., Harvard Medical School, 1915. Dr. Clason was an internist in the Hartford County area since 1917. He was on the staff of Hartford Hospital. Dr. Clason was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died December 31, 1985 at the age of 96.

FARRELL, RICHARD F., University of Vermont College of Medicine, 1942. Dr. Farrell was an orthopedic surgeon in the Fairfield County area since 1946. He was attending at Stamford Hospital and St. Joseph's Hospital. Dr. Farrell was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died January 8, 1986 at the age of 62.

GANDY, RAYMOND A., University of Virginia School of Medicine, 1927. Dr. Gandy was an obstetrician and gynecologist in the Fairfield County area since 1929. Before retiring in 1972, Dr. Gandy was a staff member of the Stamford Hospital and St. Joseph's Hospital. From 1956 to 1962 he was the director of gynecology and obstetrics and St. Joseph's Hospital. Dr. Gandy was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died January 16, 1986 at the age of 84.

KOUFMAN, WILLIAM B., Tufts Medical School, 1935. Dr. Koufman was a general surgeon in the New Haven County area since 1936. He was on the staff of The Hospital of St. Raphael, Yale New Haven Hospital and the Veterans Hospital in Rocky Hill. Dr. Koufman was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died December 7, 1985 at the age of 75.

O'BRIEN, FRANCIS H., Columbia College of Physicians and Surgeons, 1938. Dr. O'Brien was a neurosurgeon in the New Haven County area since 1951. He was clinical associate professor of neurosurgery at the University of Connecticut. Dr. O'Brien was a neurological consultant to Sharon, New Milford and New Britain hospitals and Southbury Training School. He was a founding member of the American Trauma Society and the International Association for the Study of Pain. Dr. O'Brien was a member of the New Haven County Medical Society, the Connecticut State Medical Society and the American Medical Association; died October 30, 1985 at the age of 74.

O'BRIEN, MICHAEL, College of Osteopathic Medicine, 1943. Dr. O'Brien was a general practitioner in the New Haven County area since 1952. He was a member of the Connecticut Society of Osteopathic Physicians and Surgeons. Dr. O'Brien was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died November 29, 1985 at the age of 65.

PECK, BERNARD C., Long Island College Hospital, 1931. Dr. Peck was a family practitioner in the Hartford County area since 1932. Before retiring in 1980 he was on the courtesy staff of the New Britain General Hospital. Dr. Peck was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died January 5, 1986 at the age of 82.

ROGERS, ROBERT P., Harvard Medical School, 1925. Dr. Rogers was a pediatrician in the Fairfield County area since 1929. He was a consultant in pediatrics at Stamford Hospital. Dr. Rogers retired from private practice in 1965 and joined the Peace Corps. From 1968 to 1969 he was a consultant and deputy director of the medical division of the Peace Corps. Dr. Rogers was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died December 15, 1985 at the age of 85.

SEARS, LEWIS, Harvard Medical School, 1929. Dr. Sears was an internist in the New London County area since 1933. He served as the director of the city of Norwich Board of Health from 1957 to 1985. Dr. Sears was a member of the New London County Medical Association, the Connecticut State Medical Society and the American Medical Association; died February 9, 1986 at the age of 80.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

DERMATOLOGY

Active Dermatology Practice for sale in central Connecticut. Doctor retiring; will introduce. Write CSMS, c/o DERM/JJ.

The Northeast Permanente Medical Group, P.C., the Medical Group for the Hartford Connecticut area of the Kaiser Permanente Medical Care Program's Northeast Region, is seeking a board certified or eligible dermatologist in 1986. The Hartford area currently serves over 23,000 members from two ambulatory care facilities in East Hartford and Farmington. The Medical Group is a multispecialty prepaid practice organized as a professional corporation. Applicants should be willing and qualified to provide ambulatory primary care while establishing a full-time dermatology practice. Salary and benefits are highly competitive. All inquiries and resumes should be addressed to: Daniel A. Gregorie, M.D., Regional Medical Director, Northeast Permanente Medical Group, P.C., 60 Washington Street, Suite 401, Hartford, CT 06106.

EMERGENCY MEDICINE

Full-time position available in modern, well-equipped Emergency Room. Send Curriculum Vitae to Lawrence Ward, M.D., Director of Emergency Services, Winsted Memorial Hospital, 115 Spencer Street, Winsted, CT 06098.

FAMILY PRACTICE

Northeastern Connecticut. Group of two Family Practitioners seeking third to replace a departing Family Physician. Must do obstetrics; excellent financial package; mid-sized community hospital; full privileges available. Reasonable distance from Providence. Contact Diane Fegatelli (716) 884-3700 or write 4-CS Vermont St., Buffalo, NY 14213.

Young, expanding group practice in Western Connecticut seeking BC/BE family practitioner to join family practice in existing office. Highly desirable area. No OB. CV to: Brookfield Health Associates, P.C., 940 Federal Road, Brookfield, CT 06804.

BC/BE residency trained physician to take over well-established practice in North Central Connecticut. Modern office; full hospital privileges; good coverage group. Will introduce to patients and physicians in the area. Available immediately. Please send curriculum vitae to Marjorie A. Purnell, M.D., 23 Davis Avenue, Rockville, CT 06066.

GENERAL PRACTICE

Licensed physician for full or part time. Send CV to Dr. Schlessel, 100 Broadway, North Haven, CT 06473.

Physician wanted for part time work in shoreline general practice. Experience in general practice or internal medicine essential. No night or hospital work. Inquiries can be made to Dr. R.J.N. Keer, M.D., P.O. Box 338, Clinton, CT 06413.

INSTITUTIONAL MEDICINE

Immediate opportunity for physician (female preferred) to begin developing private practice with multidisciplinary mental health group including an established Premenstrual Syndrome Clinic (oldest in Hartford). Call (203) 527-5523 or send C.V. to Clinical Director, P.O. Box 14372, Hartford, CT 06114.

INTERNAL MEDICINE

Seeking BC/BE internist to rapidly become partner in 3-½ year old general internal medicine practice. Modern, computerized office on shoreline. Office located just six minutes from Yale-New Haven Hospital. Candidate must be willing and enjoy working with elderly as there is a heavy emphasis on quality geriatric medicine and nursing home care, besides a general medicine population. If interested, please send CV to CSMS, c/o IM/PP.

Internist, BC/BE needed to join our growing HMO Network in Southwestern CT. Openings slated for March and July, 1986. If you are interested in practicing personalized, cost effective, preventive medicine with competitive salary and comprehensive fringe benefits in coastal New England, submit C.V. to: Ron Blumenfeld, M.D., Medical Director, Community Health Care Plan, 4000 Park Avenue, Bridgeport, CT 06604. (203) 371-1582.

Internist, BC/BE to join busy Internal Medicine group in Connecticut. Rapid advancement to full partnership. Send CV to CSMS, c/o IM/GD.

B/C or B/E internist sought by three physician primary care group in New Haven, Connecticut. Office well-equipped with laboratory and x-ray facilities. Initial salary with goal toward partnership. Send resume to CSMS, c/o IM/FF.

MISCELLANEOUS

Waterbury Area—Medical Director, 12-20 hrs/wk, for W.I.P.A. (Waterbury Independent Physicians Association). Responsibilities to be primary liaison between I.P.A. M.D.'s, C.H.N. (Constitution Health Network) and the I.P.A. Board. Direct Inquiries to W.I.P.A., P.O. Box 83, Oakville, CT 06779.

OBSTETRICS AND GYNECOLOGY

Excellent opportunity for young Board certified or eligible Obstetrician/Gynecologist, New London. For information call 442-4346.

Obstetrician/Gynecologist, BE/BC, to join established two doctor OB/GYN private practice in Hartford area of Connecticut. Major teaching hospital affiliations. Excellent salary and benefits including paid professional liability and health insurance, with progression to partnership. Send CV to CSMS, c/o OB/MM.

PEDIATRICS

Pediatrician, BC/BE to share practice with another pediatrician in a progressive community health center in New Haven, CT. Seeking an individual to work in a challenging and rewarding community health setting who will be part of a primary care team. In addition to clinical practice, position includes hospital responsibilities and call. Spanish-speaking helpful. Contact, Katrina Clark, MPH, Director, Fair Haven Community Health Clinic, 374 Grand Ave., New Haven, CT 06513. (203) 777-7411.

Seeking second Neonatologist for July '86 as a 400+ bed, Central Connecticut General Hospital. University of Connecticut affiliate. Responsibilities to include clinical care in busy, Level II nursery and implementation of planned expansion to designated Level II unit in regional program. Interest in management of older, acutely ill children desirable. Ample opportunity for teaching and research interests. Direct inquiries to A. M. Capriglione, M.D., Chief of Pediatrics, New Britain General Hospital, 100 Grand St., New Britain, CT 06050.

Pediatric practice for sale due to retirement July 1986. Wess established Central Connecticut—Close to Hartford and New Haven. Terms negotiable. Write the CSMS Placement Service. c/o SALE/DD.

PHYSICIANS WISHING TO PRACTICE IN THE STATE OF CONNECTICUT

INTERNAL MEDICINE

July '86. Age 30. Nat'l bds. AB cert. MD, S.U.N.Y., Downstate Medical Center, Brooklyn, NY: Int. and Res., Kings County, Downstate, (Brooklyn VA Hospital); Fellowship, Nassau County Medical Center (Gastro), NY. Seeking position as associate/partner in small group. Fully trained in all routing endoscopic procedures. Write, Frank J. Karpowicz, M.D., 200 Carman Ave., Apt. 8C, East Meadow, NY 11554.

July '86. Age 33. Licensed in Connecticut. Nat'l bds. AB cert. MD, Georgetown University; Int. and Res., New England Deaconess Hospital; Fellowship, Yale University, New Haven. Prefers group, associate or institutional type practice in a large-sized community. Write, Dean F. Markham, Jr., M.D., 815 Whitney Ave., #5, New Haven, CT 06511.

ALLERGY. Immediately available. Age 43. Licensed in Connecticut. Nat'l bds. AB elig. MD., Temple University School of Medicine; Int., Beth Israel Hospital New York, NY; Res., University Hospital, Ann Arbor, Michigan; Fellowship, Albert Einstein Medical Center, Philadelphia, PA. Wishes to relocate part time or full time near Weston, CT. Write, Harold Axe, M.D., 25 Fifth Ave., New York, NY 10003.

NEPHROLOGY. Available July '86. Age 52. Licensed in Connecticut. FLEX. AB elig. MD, Universidad Autonoma de Cd. Juarez, Mexico; Int. and Res., Lincoln Medical Center, Bronx, NY; Fellowship, Booth Memorial Medical Center, Flushing, NY. Would be interested in working in emergency room, critical care or primary care settings in a medium to large-sized community. Write, Olga F. Szabo, M.D., 351 East 84 St. Apt. 23B, New York, NY 10028.

PULMONARY. July '86. Licensed in Connecticut. Age 30. Nat'l bds. AB cert. MD, Johns Hopkins, Baltimore, MD; Int. and Res., University of Chicago, Chicago, IL; Fellowship, Yale-New Haven Hospital. Prefers group or associate type practice. Write, Ilene L. Rosenberg, M.D., 574 Skiff St., North Haven, CT 06473.

NEUROLOGY

July '86. Age 30. AB elig. MD, Int. and Res., S.U.N.Y. Stony Brook, NY. Prefers group, associate or institutional type practice in a medium to large-sized community. Currently Assistant Professor of Neurology, Temple University. Write, Richard M. Hassett, M.D., 11 N. 2nd Street, Apt. 201, Philadelphia, PA 19106.

PATHOLOGY

Feb. '86. Age 38. Nat'l bds. AB elig. MD, New York Medical College, Valhalla, NY; Int., Yale-New Haven Hospital, New Haven, CT; Res., University of California, Sacramento, CA. Prefers associate type practice. Write, Leslie Dowd, M.D., P.O. Box 546, Manchester, CT 06040.

PEDIATRICS

Immediately available. Age 43. Presently in group practice. FLEX. AB cert. MD, University of Ceylon; Int., Methodist Hospital, Brooklyn, NY; Res., Downstate Univ./Kings Co., Brooklyn, NY; Fellowship, Coney Island Hospital, Brooklyn, NY. Prefers group, associate or institutional type practice. Write, Michael A. Satchie, M.D., 4220 Patzke Lane, Racine, WI 53405.

PLASTIC SURGERY

July '87. Age 30. Nat'l bds. AB elig. MD, University of Chicago, Chicago, IL; Int. and Res., University of Michigan, Ann Arbor, MI; Fellowship, Hospital of the University of Pennsylvania, Philadelphia, PA. Seeking private practice with/or University affiliation in a large-sized community. Write, Jerrold Zeitels, M.D., #16, 240 East Montgomery Ave., Ardmore, PA 19003.

PRIMARY CARE

Feb. '86. Age 33. AB cert. MD, University of Rome, Rome, Italy; Int., Long Island College Hospital, Brooklyn, NY; Res., Illinois Masonic Medical Center, Chicago, IL. Prefers group, associate or HMO type practice in a medium-sized community preferably in western Connecticut. Write, Eli R. Goldner, M.D., 2841 West Rosemont, Chicago, IL 60659.

PSYCHIATRY

Immediately available. Age 59. Licensed in Connecticut. Presently in practice. AB cert. MD, London University, England; Int., Bridgeport Hospital, Bridgeport; Res., Cornell University, NY; Fellowship, National Neurological Hospital, London, England. Prefers part time employment in a medium-sized community. Write, Colin B. Cook, M.D., 373 Strawberry Hill Ave., Stamford, CT 06902.

RADIOLOGY

Immediately available. Age 59. Licensed in Connecticut. Nat'l bds. AB cert. MD, Georgetown University School of Medicine; Int., St. Francis Hospital, Hartford, CT; Res., Temple University Hospital, Philadelphia, PA. Seeking part time, perdiem, or full time position in Diagnostic Radiology. Write CSMS c/o JRG/RAD.

Feb. '86. Age 45. Licensed in Connecticut. Nat'l bds. AB elig. MD, Odessa Medical Institute, USSR; Int., Medical Institute's Hospital, USSR; Res., Bridgeport Hospital, Bridgeport, CT; Fellowship, University of Connecticut Medical Center, Farmington, CT. Has a specialty in Nuclear Medicine and Nuclear Cardiology. Has no preference to type of practice or size of community. Write, Michael Sedlovsky, M.D., 191 Barry Scott Dr., Fairfield, CT 06430.

Immediately available. Age 33. Presently in practice (part-time). Licensed in Connecticut. Nat'l bds. AB cert. MD, George Washington University School of Medicine, Washington, DC; Int. and Res., SUNY, Upstate Medical Center, Syracuse, NY; Fellowship, CT/Ultrasound. Seeking locum tenens, part-time or permanent position. Will consider any type of practice or size of community. Write, Douglas B. Bober, M.D., 47 Strawberry Lane, Manchester, CT 06040.

Noninvasive Evaluation of Aortic Stenosis

JOSÉ C. MISSRI, M.D.

ABSTRACT – Two dimensional echocardiography has proven very useful in assessing aortic stenosis, but the technique is limited in certain groups of patients and is unable to quantify a transvalvular pressure gradient. Advances in Doppler ultrasound techniques have made it possible to noninvasively measure velocity of flow across a stenotic aortic valve and to calculate the pressure gradient. The attributes and limitations of these new diagnostic methods are delineated in this article.

The traditional clinical evaluation of aortic stenosis (AS) depends heavily on physical examination supplemented by chest x-ray, the electrocardiogram and the phonocardiogram. Although these approaches have important bearings on the likelihood of the diagnosis, they do not always assure the presence or absence of AS. With the advent of echocardiography, left ventricular outflow obstruction, and, in particular, AS can be imaged directly. As a result, determination of the presence or absence of AS with echocardiography has become a definitive test. Once the presence of aortic stenosis is ascertained, however, the noninvasive determination of its severity is a considerably more difficult challenge. This review focuses on the role of echocardiography, in particular two-dimensional echocardiography, and of Doppler echocardiography in this regard.

Two-Dimensional Echocardiography

Two-dimensional echocardiography has replaced the M-mode as a means of assessing orifice size, because the linear dimension of the orifice sampled by the unidimensional M-mode beam is not necessarily representative of the stenotic aortic orifice in two spatial dimensions. Alternative attempts using M-mode to predict peak left ventricular pressure and hence a transaortic gradient from formulas for wall stress have been somewhat successful in children but are not helpful in adults with coronary disease or left ventricular dysfunction.

Few two-dimensional echocardiographic studies exist that address AS severity in adult patient groups (Figure 1). The early work of Weyman et al[1] indicated that different degrees of AS could be recognized by long-axis views of the aortic valve with two-dimensional echocardiography. In this study of 28 patients, 15 individuals were classified by catheterization criteria as having severe AS (peak gradient 75 mm Hg or calculated valve area 0.75 cm^2 to 1.0 cm^2, or both), 5 as having moderate AS (peak gradient 50 mm Hg to 75 mm Hg or valve area 0.75 cm^2, or both and 8 patients as having mild AS (peak gradient less than 50 mm Hg).

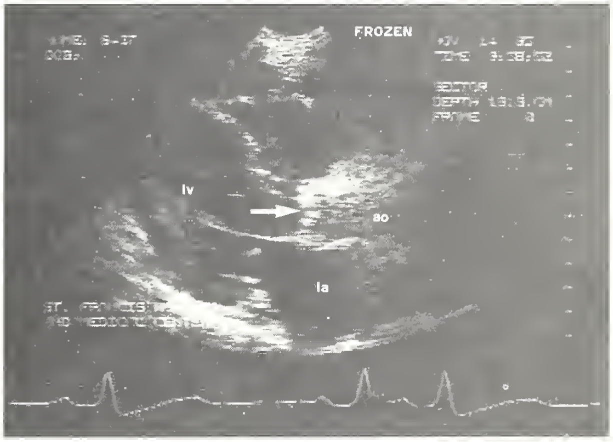

Figure 1

Long-axis of a patient with severe calcific aortic stenosis. There is heavy calcification of the aortic valve and inadequate aortic valve orifice at end systole (arrow). lv = left ventricle; la = left atrium; ao = aorta.

The maximum leaflet separation measured in systole as a diameter of the inner aspect of the leaflet echoes was 7.9 ± 1.8 mm (range, 4 mm to 11 mm) in the severe sub-group, 11.6 ± 2.3 mm (range, 9 mm to 15 mm) in the moderate sub-group, and 16.9 ± 2.0 mm (range, 14 mm to 20 mm) in the mild sub-group. In 25 patients without evidence of aortic valve disease, this intercusp distance averaged 20.5 ± 2.8 mm (range, 15 mm to 26 mm).

This study indicated that sub-groups of patients with at least some degree of AS were statistically

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JOSÉ C. MISSRI, M.D., Associate Director, Section of Cardiology, Saint Francis Hospital and Medical Center, Hartford, CT; Assistant Professor of Medicine, University of Connecticut School of Medicine, Farmington, CT.

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distinguishable and clearly different from normal individuals. It further confirmed that two-dimensional echocardiography provided better sub-group differentiation than M-mode echocardiography in distinguishing degrees of aortic obstruction.

Despite these encouraging findings, further progress has not been made in dealing with individual patients rather than with differentiating patient sub-groups using two-dimensional echocardiography. Indeed, statistically significant sub-group discrimination of patients with AS has been possible with other non-invasive techniques. For example, such differentiation can be achieved with carotid pulsed tracings and phonocardiography, both more indirect techniques than echocardiography that clearly are not heavily relied on in modern practice.

In dealing with an individual patient, the problem of defining AS severity is more challenging because the clinical decision to proceed or not to proceed to valve replacement must be as close to 100% correct as possible. If this distinction could always be made with 100% accuracy using two dimensional echocardiography, the need for catheterization to evaluate this lesion could be averted.

How well would we fare if we use two-dimensional echocardiography in this manner? One answer to this question has been provided by DeMaria et al.[2] These investigators measured maximum systolic intercusp distance, although they extended the measurement to short axis and apical views. Their study population of 85 patients had some degree of AS at cardiac catheterization; 72 (85%) had satisfactory two-dimensional echocardiograms. A valve area of 0.75 cm^2 at catheterization was used to distinguish severe from non-severe obstruction. Leaflet separation correlated poorly with aortic valve area or peak transvalvular gradient; the linear correlation coefficient between echo measurements and catheterization gradient was less than 0.4 in either case. Forty-two of 46 patients with catheter proved severe AS had leaflet separation of 8 mm (sensitivity 91%), but only 17 of 26 patients with non-critical AS had leaflet separation greater than 8 mm (specificity, 65%: predicted value of a positive test, 82%).

Stated differently, if, in a given patient, an adequate aortic valve orifice is not imaged by two-dimensional echocardiography, nearly a 20% chance still exist that this patient does not have severe AS (i.e., false-positive results are not rare). Furthermore, if one uses a larger leaflet separation value to improve sensitivity, specificity will decrease (i.e., the incidence of false-positives will increase).

A subsequent study involving 82 patients reported a leaflet separation less than 8 mm to be 97% predictive of severe AS.[3] With this group's study procedure and population, false positives were rare. In marked contrast to this experience is another study that evaluated AS severity using aortic-leaflet excursion, with no or minimal excursion considered to be a marker of severe AS and more than 1 cm of excursion indicative of mild AS.[4] In only 22 (39%) of 57 patients was there agreement between two-dimensional echocardiographic and catheterization findings. Thus, I believe that when adequate intercusp separation (greater than 15 mm) is seen on two-dimensional echocardiography, severe AS is definitely not present. When a separation of 8 mm to 15 mm is observed, severe stenosis is unlikely (approximately a 10% probability). When the leaflet separation is less than 8 mm, severe stenosis is likely, but this probability is only in the 60 to 80% range.

Doppler Echocardiography

Doppler echocardiography offers a new non-invasive method for evaluation of AS by direct measurement of flow velocity, which increases as the valve area is reduced (Figure 2). The use of continuous-wave Doppler ultrasound to measure valvular gradients was first reported in 1976 by Holen et al.[5] They demonstrated that the pressure gradient across a stenotic valve could be determined noninvasively using velocity measurements obtained by Doppler ultrasound techniques. Subsequent studies by Hatle et al[6] verified these observations in mitral stenosis and extended them to include patients with AS.

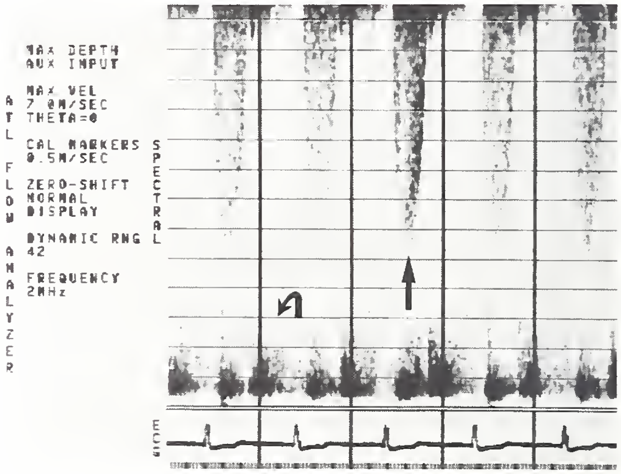

Figure 2

Doppler study obtained from cardiac apex. The direction of the aortic jet is away from the transducer. The maximal velocity as shown on the spectral display is 4.4 m/s (vertical arrow) and the calculated peak aortic valve gradient 77 mm Hg. During diastole flow toward the transducer (curved arrow) is present because of aortic regurgitation.

To date, quantitative Doppler applications appear to be most valuable in predicting the gradients across the stenotic valves. This has been particularly true both in the congenital and acquired forms of AS. When a valve is stenotic, flow velocity increases through the restricted orifice. The abnormally high velocity of the flow jet that emanates from such a restricted orifice can be related to the pressure gradient across the valve by a simplification of the Bernoulli equation, which states that the peak gradient is equal to 4 times the square of the peak velocity (pressure gradient $= 4 \cdot V^2$).

The Doppler examination critically depends on appropriate sampling (i.e., the Doppler beam must be parallel to flow) of a highly localized abnormal jet at or just distal to the obstructive aortic valve orifice. If this jet is present but not detected, the test will be falsely negative. Experience to date indicates that positive tests occur only as a result of abnormally high velocity jets due to severe AS. Thus, in theory, the Doppler examination should complement two-dimensional echocardiography since it has the potential to evaluate further those patients who appear to have severe AS on two-dimensional echocardiograms. The Doppler studies to date, however, have been independently reported evaluations, without information obtained by two-dimensional echocardiography.

The initial studies were dominated by patients in pediatric age groups. Two such studies demonstrated excellent correlation between Doppler-estimated gradients and transaortic valvular gradients at cardiac catheterization.[7,8] Adults with AS are more challenging to study because the high-velocity jet of AS in adults has a greater likelihood of being eccentric due to irregular valvular calcification. Such jets may not be parallel to the interrogating Doppler ultrasonic beam, producing a Doppler frequency shift that can underestimate true jet velocity. At our Institution, we report approximately an 80% success rate in obtaining adequate Doppler studies in patients with AS. This is similar to the work of Stam and Martin who reported an 81% success rate in 32 patients with AS.[9] Although retrospective, this study showed an excellent correlation of directly measured and Doppler-estimated gradients, with a close-fitting distribution of points about the line of identity in their regression relationship. In fact, all patients with peak-to-peak catheterization gradients greater or less than 50 mm Hg were correctly identified using Doppler. This study, however, points out the additional important caveat that in patients with severe AS and low cardiac output, a large gradient (> 50 mm Hg) need not be present. In low-output states, therefore, severe AS can be present but still not be detected if jet velocity measurements are relied on as the sole distinguishing criteria. Since Doppler echocardiography is performed in conjunction with standard two-dimensional echocardiography, one is generally alerted to clinical situations in which low flow states of low ejection fraction coexists. One should thus employ the Doppler-derived pressure gradients in conjunction with other parameters of ventricular performance.

It must be emphasized that the Doppler-derived aortic valve gradient is the maximal instantaneous pressure gradient between the aorta and the left ventricle. This value tends to be higher than the catheterization-derived gradient, in which the difference between the peak aortic and peak left ventricular pressures is reported, because these occur at different points in time during systole. This difference is greater with mild to moderate degrees of stenosis. Nonetheless, the correlation between the mean decreases in pressure determined by both methods remains excellent. Measurement of the Doppler gradient at midsystole appears to offer a more accurate correlation with the peak-to-peak catheterization gradient and eliminates the problem of overestimation.[10]

The simple prediction of pressure gradient is not as useful to the clinician as is valve area since the pressure gradient may change substantially over time depending on afterload, autonomic tone, and left ventricular function. The cardiac output and heart rate likewise have major impact on the valculated valve area and may themselves change significantly with time. Accurate definition of valve area has been demonstrated in a group of pediatric patients, the majority of which had pulmonic stenosis, with the use of Doppler velocities.[11] Only recently has a study been performed using Doppler-derived flow velocities in the calculation of valve area in the older patient with calcific AS.[12] Aortic valve area (AVA) was calculated with the equation: AVA = CO/(SEP x mean velocity), where CO is cardiac output measured by thermodilution (right heart catheterization) and SEP is the systolic ejection period derived from the Doppler tracings. The resulting value was compared with valve area calculated from cardiac catheterization data and an excellent correlation was noted (r = .99).

Several potential problems remain regarding the use of Doppler ultrasound to quantitate AS. Foremost is the possible inability to obtain adequate Doppler recordings of the high-velocity aortic jet. It should be noted, however, that the Doppler ultrasound studies must be done slowly and carefully; often up to 30 minutes is necessary for the velocity recording alone. In addition, obesity or concomitant lung disease can make adequate tracings unobtainable in some patients. An inadequate Doppler tracing would lead to an underestimation of the maximal velocity, and therefore an over estimation of the valve area. Theoretically, it would not be possible to underestimate the valve area, because a jet of falsely high velocity should not be obtainable. However, one should be especially cautious when the valve is both stenotic and regurgitant. In this situation the gradient may be increased because of the high forward flow across the valve.

There is now available a new technology that combines the anatomic imaging of two-dimensional echocardiography with real-time visualization of intracardiac blood flow (color-flow mapping) superimposed on a two-dimensional echocardiographic display. Doppler color-flow of a stenotic aortic valve will show a narrow band of flow emitted from a restricted valve orifice, seen as a blue jet entering the aortic root. The narrowness of the jet is inversely proportional to the severity of the stenosis. The technology shows not only the spatial orientation of jets and the area of highest velocity but also the angular orientation of jets from the stenotic lesions. This allows one to perform guided continuous-wave Doppler interrogations across the highest velocity area and to perform rational angle correction within the plane of imaging.

Conclusions

Two-dimensional Doppler offers for the first time noninvasive, real-time two-dimensional imaging of simultaneous intracardiac morphology and flow. Continuous-wave Doppler echocardiographic examination by an experienced echocardiographer can reliably estimate the maximum instantaneous and mean pressure gradient in adults with AS. This information, along with other noninvasive data, will aid in the clinical management of such patients.

In the final analysis, of course, evaluation of the patient who may have severe AS is not restricted to information from a single diagnostic test but can be importantly influenced by many individual circumstances; history, clinical context, physical findings, and other laboratory information all can have important decision-determining influences.

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Interpreting Spinal Fluid Cultures in Candidaisis

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ABSTRACT— The results of 8,000 CSF specimens cultured for candida at the Yale New Haven Hospital over a four and a half year period has been recorded. There were four patients with positive cultures. Three had proven candida meningitis, one was regarded as a false positive, possibly incorrectly. Only nine of 48 CSF cultures were positive prior to the initiation of therapy in the three patients with proven candida meningitis. It is concluded that positive CSF cultures for candida should not be regarded as contaminated if there is pleocytosis, even if candida infection exists outside the nervous system.

Infections of the brain and nervous system by Candida species have been reported with increasing frequency in recent years,[1-3] yet physicians often mistakenly assume that candida growing from the cerebrospinal fluid (C.S.F.) cultures is a contaminant, especially if another source of candida infection is present or if growth from CSF cultures is delayed. Since an important factor in effectively and successfully treating candida meningitis is diagnosing the disease early,[1] it may be important to take seriously any positive candida growth from the CSF, even if there is known candida in other organs or if candida grew from CSF cultures only after several days delay. To determine what the chances of contamination by candida actually are, we performed a study of the results of all the CSF cultures for candida at the Yale New

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Haven Hospital that were reported during a four and a half year period.

Methods

The results of all CSF cultures performed at the Yale New Haven Hospital over a fifty-four month period were reviewed. Specimens of CSF had been sent to the microbiology laboratory. Gram stains and India ink preparations were routinely performed on all specimens as were fungal cultures. CSF was incubated in sheep blood, chocolate, or thioglycolate broth. The sheep blood and chocolate cultures were observed for 5 days before being termed negative. The thioglycolate broth was held for two days. The results of all the cultures that did grow candida were recorded and the corresponding patient records were reviewed to determine if the diagnosis of candida meningitis was entertained and the patient treated. The response to treatment was noted. In cases where more than one lumbar puncture was reported, the number of cultures positive for candida was recorded. In this way the proportion of "false negatives" was calculated.

Results

From November 1980 to April 1985, more than 8,000 lumbar punctures were performed at the Yale New Haven Hospital and sent for fungal cultures. Of these, the CSF of only four patients grew out candida (all were identified as Candida Albicans).

The clinical records of these indicated that three (patients 1, 2, and 3, Table 1) had been diagnosed as having candida meningitis. Each of these had accompanying predisposing factors. The neurological signs and symptoms were non-specific and included lethargy, seizures, fever, chills, pleocytosis, and, in two patients with lumbar parameningeal foci, lumbo sacral pain and foot drop (patients 1 and 2).

The CSF of all four patients consistently revealed pleocytosis. There were variable elevation of the protein content and variable depression of the sugar concentration. With the exception of the one patient who was not diagnosed as having candida meningitis (patient 4), all were treated with Amphotericin-B and two received 5-fluorocytosine in addition. Prior to treatment, patients 1, 2 and 3 had a total of 48 lumbar punctures of which nine were positive for candida. An example is shown in Table 2.

The three patients who were treated were discharged, improved, though one subsequently relapsed.

The one assumed false positive was a 35 year old woman with a recurrent clivus chordoma who had received radiation and steroids following intra oral surgery for the tumor. This positive CSF culture was regarded as a contaminant, as subsequent cultures of CSF were negative. Accordingly, she has not been treated for a candida infection. However, this woman still has persistent, unexplained elevated CSF protein and pleocytosis.

Discussion

Clinically, candidaisis must be taken seriously. It has become an increasingly common cause of meningitis. The mortality rate in patients receiving inadequate or no antifungal therapy is high (more than 90%), while those patients given appropriate antifungal therapy have a mortality rate of 38%. An important factor associated with poor prognosis is a diagnostic interval of over two weeks after symptomatic onset.[1]

Candida meningitis tends to strike patients with

Table 1
CLINICAL DATA IN FOUR PATIENTS WITH CSF CULTURE POSITIVE FOR C. ALBICANS

Patient	*Age*	*Sex*	*C. Albicans in other Organs*	*Predisposing Factors*	*Diagnosis*	*Neurological Signs, Symptoms*	*Therapy*	*Response*
1	58	M	– –	-alcoholism, -cirrhosis -porta caval shunt -?adult immune deficiency syndrome	C.Meningitis	-seizures -organic brain syndrome -foot drop -pleocytosis	Amphotericin B	Improved but relapsed
2	45	M	Mouth	-renal transplant -immurosuppressin -steroid use	C.Meningitis	-headache -lethargy -chills, fever -foot drop -lumbar pain -pleocytosis	Amphotericin B 5-F C	Improved
3	70	F	Vitreous Fluid	-Crohn's disease -steriod use -diabetes -renal failure -anemia	C.Meningitis	-fever -pleocytosis	Amphotericin B 5-F C Rifampin	Improved
4	35	F	Mouth	-clivus chordoma (removal via oral approach) -radiation -steroid use	depression unexplained CSF changes	-depression -headache -intermittent fever -pleocytosis	– –	– –

Table 2
SERIAL CEREBROSPINAL FLUID RESULTS IN PATIENT #2

Date of Lumbar Puncture	*Pressure* (mmH_2O)	*Protein* (mg per dl)	*Glucose* (mg per dl)	*Leukocytes** (per mm^3)	*Candida* Culture	Comment
1/5	normal	28	62	220	neg	
1/6	210	23	62	640	pos	Growth only after 4 days
1/8		21	59	580	neg	
1/10			50	840	neg	
1/17		46	39	418	neg	
1/22		46	25	842	neg	
1/25		42	28	537	neg	
2/3		68		218	pos	
2/7		50	30	55	neg	
2/12	160	120	32	86	neg	
2/20		89	42	99	neg	
3/1		50	31	81	neg	
3/5		93	30	100	pos	
3/6		136	43	253	neg	
3/20		117	44	240	neg	
3/23		61	29	670	pos	Amphotericin-B started
5/4			30	170	neg	
5/16	240	186	20	4000	pos	shaking, chills headache, fever
5/18		140	34	83	neg	
5/21	180	165	35	73	neg	
5/25	190		53	33	neg	
5/28	190	125	33	43	neg	
6/23	270	140	33	2100	pos	lumbosacral pain, chills, fever
6/25	250	100	31	337	neg	
7/3	220	107	37	121	neg	
7/12	240	100	41	13	neg	
7/13	260	175	26		neg	
7/25		107	49	7	neg	
8/8		104	87	10	neg	total Amphotericin-B completed (4gms)

*Percent of granulocytes was consistently greater than 60

predisposing conditions. These include: prior antibiotic therapy, the use of systemic adrenocortical steroids, indwelling intravascular catheters, diabetes mellitus, and other serious chronic diseases,[4] but no one is completely immune from infection. If clinicians only consider the diagnosis in patients with classic predisposing factors or those who consistently grow the fungus from multiple CSF specimens, they may lose valuable time in correctly diagnosing the disease. The most important factor in the diagnosis and proper treatment of candida meningitis is responding correctly to cultures of the CSF.

A single, isolated growth must be taken seriously because false positives are rare: at most, one in 8,000 CSF specimens. The frequency of false negatives is much higher: in the three patients diagnosed as having candida meningitis, candida grow from only nine of 48 CSF specimens prior to the institution of therapy.

Two articles illustrated this point. Edelson[5] presented the case of a patient who had seven lumbar punctures which were all negative for candida until the eighth, performed a few days before the patient died of candida meningitis, grew the yeast from a 40cc specimen of CSF. The author's suggestion was to do less frequent lumbar punctures, but to obtain more fluid (30-40 ml) when candida is suspected.

Holyst[6] presented the case of a middle aged man with a large cerebellar abscess due to c. albicans. The mass was surgically removed and identified as a candida abscess; the patient was discharged after therapy with Amphotericin-B but died three weeks later due to complications of recurrent candida meningitis. Not once during his entire illness did candida grow from numerous CSF specimens.

When CSF cultures are positive in patients who are known to have candida in other organs, the temptation to consider that the CSF sample has been contaminated should be resisted. In our study, of four patients with candida growing from CSF, three (patients 2, 3, 4) had candida growing in the mouth or vitreous (Table 1). There is a high frequency of widespread candida in combination with candida meningitis. Parker[7] evaluated 19 autopsies in patients with cerebral candidiasis and found there to be candida growing in other organs in every one of these patients. The most common sites were kidney, heart, gastrointestinal tract, lung and blood vessels. Therefore, a positive CSF culture with pleocytosis, in the presence of candida in organs outside of the nervous system must be considered candida meningitis unless proven otherwise.

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Fournier's Gangrene, or Necrotizing Fasciitis

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ABSTRACT— Fournier's gangrene is a rare but devastating form of necrotizing fasciitis involving the male genitalia and perineum. Though originally described as idiopathic there are now multiple etiologies identified. Successful therapy depends on early diagnosis and aggressive surgical debridement. Morbidity and mortality are high, and long term hospitalization is the rule. Two recent cases are presented to illustrate the fulminant course this disease follows. Emphasis is placed on creating a better awareness of the entity and on reinforcing the concept that this is a true surgical emergency.

In 1883 Fournier reported five patients with unexplained gangrene of the genitalia.[1] The syndrome of necrotizing genital fasciitis has since born his name. It is a rare phenomenon, having been reported in the literature less than four hundred times.[2] Initially this disease was characterized as arising in young healthy men in an abrupt and rapidly progressing fashion. Also it was thought to be idiopathic in origin. In 1985 Fournier's gangrene is seen to occur in older males, has a more indolent course, and has an identifiable etiology. The following case reports will illustrate the natural history of this disease.

Case Reports

Case 1: An 83-year-old white male arrived to the emergency department moribund, responding only to painful stimuli. No history was obtainable. Vital signs revealed a temperature of 102°, pulse 122, respiration 40, blood pressure 105/90. Pertinent physical findings included extreme dehydration, and an erythematous lower abdominal wall. The penis, scrotum, perineum, and inner thighs were grossly edematous and erythematous, and non-creptant with a 5 x 5cm gangrenous area on the scrotum. Fournier's gangrene was diagnosed, and after initial resuscitative measures, the patient was taken to surgery. After sigmoidoscopy revealed no rectal involvement, a radical debridement of necrotic tissue extending from the anterior abdominal wall to the perineum, groin and genitalia was undertaken. A stricture was discovered in the urethra with a proximal 2 x 4cm necrotic mass. This was suspected to be an abscess created by extravasated urine that served as a nidus for the subsequent fulminant infection. A suprapubic catheter was placed at the end of the operation. Peptostreptococcus was cultured from the wound. The patient spent the next two months in and out of intensive care and required six operative procedures. The patient succumbed at length to multisystem organ failure as a result of intractable sepsis.

Case 2: An 81-year-old white male was admitted for constipation after an out-patient barium enema. The patient responded to laxatives but the next day suddenly became toxic with high fever and scrotal-perineal erythema. Fournier's gangrene was diagnosed and the patient was taken to surgery following initial resuscitation. Wide debridement was carried out along with orchidiectomy and loop colostomy. The patient subsequently required three debridements under general anesthesia and four split thickness skin grafts to cover the wound. Cultures grew E. Coli, Pseudomonas and Enterococcus. The patient was discharged after four months of hospitalization.

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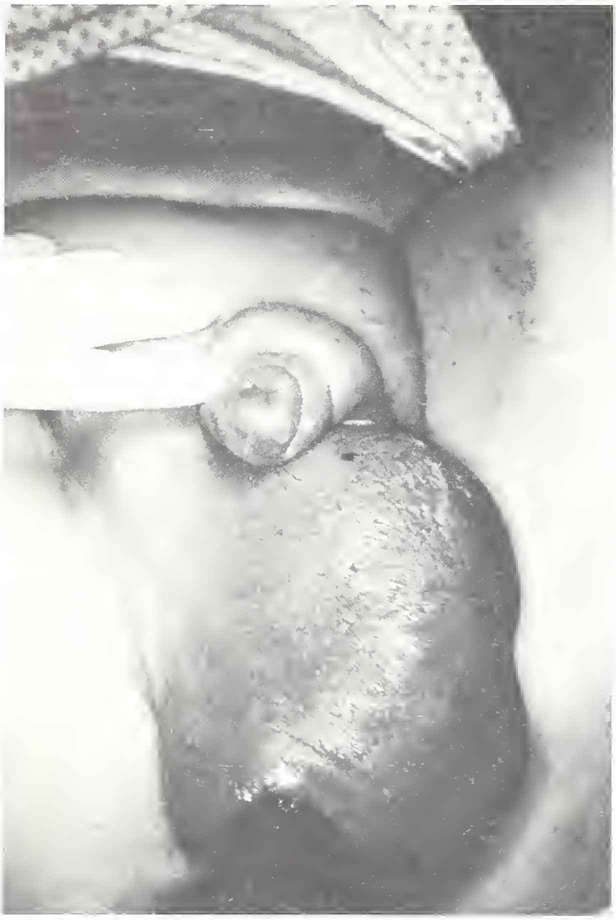

Figure 1
Patient in case number one as he presented to the emergency department. Note tense scrotal edema, inguinal erythema, and scrotal gangrene.

These cases point out that necrotizing genital fasciitis is indeed a surgical emergency. Yet even with expedient management morbid sequellae seem to be the rule rather than the exception. This is because patients often present late, when the infection is in the fulminant stage. The early signs and symptoms can be quite mild. Patients may think little of the symptoms of perineal pain and swelling and perhaps receive only low dose antibiotics by unwary physicians. Conversely, patients debiliated with senile dementia or chronic alcoholism may not be able to voice complaints until and advanced stage is reached. In fact, patients, such as in case one, may present so profoundly ill that no history or early diagnosis are possible.

Fournier initially described this syndrome in young men, yet today it is seen more commonly in older individuals. Various series indicate average ages between 51 and 58.[2-5] Some authors note the phenomenon that younger patients have the more dramatic, rapidly progressing form of the disease that was initially described by Fournier, while the older patients have the indolent course as is more commonly seen today.[6] The cause of this is uncertain.

Fournier's gangrene is not an idopathic syndrome as was first reported. Rather, specific colorectal and urogenital factors have been identified. (see Table 1) In case one a urethral stricture with proximal extravasation of urine may have created a breeding ground for bacteria. An abscess formed in the vascular corpus spongiosum and quickly spread through the fascial planes of the perineum and scrotum. The infection dissected through Colles' fascia to Scarpas' fascia and through the layers of the abdominal wall. This extensive degree of necrosis is commonly found. Pathologic sections reveal small vessel thrombosis, edema and acute inflammatory cells.[7]

The obliterative endarteritis that is found helps establish an environment favorable for growth of anaerobes, particularly Bacteroides, Peptostreptococcus and Clostridia. However, the infection is usually a mixed flora, and E. Coli, Enterococcus and Klebsiella represent commonly found aerobes. That multiple organisms are isolated has suggested to some authors that a synergism between various stains of bacteria accounts for the fulminant progress of this disease.[2-5] Broad spectrum antibiotics are indicated, generally an aminoglycoside, penicillin and metronidazole or clinamycin pending cultures.

Treatment begins with basic resuscitation for dehydration and sepsis, including cardio-respiratory support and fluid and electrolyte replacement. Aggressive and early surgical debridement remains the cornerstone of therapy.

Table 1
PROPOSED ETIOLOGIES

(1) Iatrogenic	*(2) Local Trauma*	*(3) Urinary Tract Diseases*	*(4) Perianal Disease*
Hemorrhoidectomy	Chemical Burn	Prostatitis – Epididymitis	Perirectal Abscess
Hydrocoelectomy	Thermal Burn	Urethritis – Cystitis	Anal Fistula
Orchiectomy	Insect and human bites, scratches	Urethral Stricture	Fissure-in-ano
Herniorraphy	Anal Intercourse	Bladder Carcinoma	Perforated Rectal Diverticulitis
Vasectomy			Perforated Rectal Carcinoma
Cystostomy			Crohns Colitis
Foley Catheterization			
Circumcision			

This entails wide excision of all necrotic areas involved until viable tissue is encountered. If there is any question as to the extent of spread the most prudent course of action would be to initally excise only clearly necrotic tissue and plan to operate in 24 hours to ascertain the viability of remaining questionable areas. The literature indicates patients need multiple operative procedures as did the two patients in this study.[3-5] Although these two patients needed orchiectomy, the testicles can often be spared after skeletonization as they are blessed with a separate blood supply. Urinary diversion through a suprapubic cystostomy is occasionally necessary, particularly in the presence of urethral stricture. If the rectum has been involved either primarily or secondarily a diverting colostomy may be indicated. Finally, it is important to search diligently for any occult perirectal process such as fistulae that may increase morbidity if not treated early.

Recent studies propose the use of hyperbaric oxygen as an adjunct to surgical debridement.[8] Such treatment, while surely inhibiting growth of anaerobic bacteria, may actually enhance reproduction of aerobic organisms such as E. Coli. The utility of this mode of therapy is therefore questionable, and certainly has no role in delaying surgical debridement.

The high morbidity attending this disease can be reflected by the average length of hospital stay, two to three months in various series.[3,4] Patients need intensive care monitoring initially with cardiorespiratory support and hyperalimentation. Antibiotics are essential, but in no way do they replace surgical debridement. With advanced degrees of muscle necrosis myoglobinuria can occur which may necessitate dialysis. Fastidious wound care is important to limit further tissue damage and leave options for later skin closure. If therapy has been successful split thickness skin grafting has given good results.[8]

Fournier's gangrene is rare, but devastating. Mortality remains high despite aggressive surgical management (30-50% in mortality series).[2-5] Patients usually present in a late stage of the disease in florid sepsis. Subsequent multisystem organ failure is most often the cause of death. Morbidity and mortality may be reduced by earlier diagnosis. Toward this end, the physician should suspect seemingly minor perineal and periurethral infections, especially in patients with altered immune responses as in diabetics. With a higher index of suspicion patients may not present in such a fulminant stage. Prompt, aggressive surgical debridement offers the only chance for a successful recovery.

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Pregnancy in Women with Adult Polycystic Kidney Disease

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ABSTRACT– Adult polycystic kidney disease (APKD) is an autosomal dominant renal disorder present in approximately one in 500 routine autopsies. While pregnancy has little effect on the progression of the renal disease, many of the manifestations of APKD, such as hypertension, pyelonephritis, hematuria, renal calculi and even renal failure, can influence the course and management of the pregnancy. Four cases of pregnancies in women with APKD are presented. APKD and its implications for pregnancy outcome are discussed. Outlook for a satisfactory pregnancy is favorable unless severe hypertension or renal compromise are present. However, urinary tract infections must be meticulously screened for and aggressively treated. It must also be considered that one half of the offspring will develop APKD.

Adult polycystic kidney disease (APKD) is an autosomal dominant hereditary disorder with virtually 100 per cent penetrance if affected persons are followed to the eighth decade.[1] Its incidence is reported to be one in 500 in routine autopsies.[1,2] Although APKD is associated with hypertension, renal calculi, flank pain, frequent infection, hematuria and nocturia, these are often not manifest until the third or fourth decade,[3] well into reproductive years. Hepatic cysts are present in 20 to 46 per cent of patients with APKD,[4] but these are usually asymptomatic. APKD is slowly progressive to renal failure in most cases. There is no treatment for this disorder other than aggressive treatment of infection and renal calculi and prevention of trauma.

The occurrence of pregnancy in women with APKD does not influence the progression of the renal disease, but the symptoms of APKD, such as hematuria, hypertension and pyelonephritis may influence the course and management of the pregnancy.[5] We present the cases of four gravidas, two of them sisters, with previously diagnosed APKD. We will then discuss the management of pregnancy and reproductive counseling of women with APKD.

Case Reports

Case 1: D.C. is a 31-year-old G2P1001 first seen in September, 1983 at 12 weeks gestation. Her father had documented polycystic kidney disease with hypertension and had died of pneumonia at age 47. Her mother and siblings were unaffected. A brother had diabetes mellitus. The patient had been diagnosed as having APKD in 1981 by intravenous urogram and renal ultrasound. She subsequently had an uncomplicated pregnancy with a spontaneous vaginal delivery at term in 1982. Except for several urinary tract infections and occasional back pain, her kidney disease has been asymptomatic. However, a 24 hour urinalysis performed in early 1983 showed 500 mg of protein and a creatinine clearance of 48 ml/min.

Her past medical history is also positive for a penicillin allergy and mitral valve prolapse diagnosed by echocardiogram. She takes no medications on a regular basis.

Physical exam on initial visit was within normal limits, except for a midsystolic click and a uterus consistent with a 12 week pregnancy. Blood pressure was 130/84, urine was negative for protein, hemoglobin was 12.4, hematocrit 39.8 per cent, and blood type was 0 positive.

The pregnancy progressed normally, with blood pressures remaining in the 120 to 130 over 80 range, until 34 weeks gestation when the patient had an episode of painless hematuria. An ultrasound done at that time revealed bilaterally cystic kidneys with a 10 cm left renal cyst. There were also several cysts of the liver. The fetal kidneys appeared normal. Her BUN was 7 and serum creatinine 0.7. A 24 hour urine collection showed a sample of 2940 ml with 235 mg of protein and a creatinine clearance of 93 ml per min. There was + + + + blood. Urine culture was negative.

The patient was hospitalized and placed on bedrest. Hydration was ensured through intravenous infusion of crystalloid. Her blood pressure remained around 120/80. She was discharged three days later with relative clearing of the hematuria.

Weekly nonstress tests were reactive. At 37 weeks gestation, an amniocentesis was performed. L/S ratio was 2.6, PI was 0.59 and PG was 0.09. Pitocin induction was started, and a 7 lb. 14 oz. male infant was delivered four hours later with no complications. Apgars at 1 and 5 minutes were 9 and 9 respectively. Cefazolin was given intravenously just prior to delivery for prophylaxis for the mitral valve prolapse. Blood pressure in labor was 130/90. After a normal postpartum course, the patient and infant were discharged on the third day after delivery. Follow-up on the infant is not available.

Case 2: K.F. is a 29-year-old white female G1P0 first seen in March, 1984 at 14 weeks gestation. Earlier that year, she had been diagnosed as having APKD by ultrasound examination showing bilateral renal cysts, the largest being 12 cm in diameter. There was also a cyst seen in the liver. She gave no history of urinary tract infections or hematuria. APKD screening was done because of the presence of the disease in her father, 2 siblings and 2 uncles. Her father suffered from hypertension and congestive heart failure.

Other than symptomatic hypoglycemia controlled by diet and several knee operations, the patient's past medical history was benign.

Blood pressure at initial prenatal visit was 128/86, hemoglobin 12.3, hematocit 35.5 per cent, blood type 0 positive. Urine was negative for protein. Because of persistent diastolic blood pressures of greater than 90 mm Hg, alpha methyl dopa of 250 mg tid was begun at 33 weeks gestation. This was increased to 500 mg bid with no effect on blood pressure. BUN was 16, serum creatinine 0.5 uric acid 4.7, urine protein 19 mg per day and creatinine clearance 166 ml/min. A one hour 50g glucose screen was 90 mg/dl. Weekly nonstress tests were reactive, the fetus remained in a frank breech presentation.

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At 38 weeks gestation, blood pressure was 136/98 with + proteinuria. An amniocentesis showed an L/S ratio of 3.1, P.I. of 1.58, P.G. of 0.26. A primary low transverse cesarean section was done and a 6 lb 12 oz. male infant with 1 and 5 minute Apgar scores of 9 and 9 was delivered from the frank breech position without difficulty.

After delivery, aldomet was discontinued, and blood pressure remained essentially unchanged. The patient and her infant were discharged home on the fifth postoperative day after an uneventful hospital course. At 3 years of age, the infant is doing well.

Case 3: N.M. is the 30-year-old sister of K.F. who was diagnosed as having APKD in 1982. A renal ultrasound showed bilaterally cystic kidneys with the largest cyst being a 4 cm cyst of the upper pole of the right kidney. She had had an abortion at 10 weeks gestation in 1977 and presented for prenatal care at 11 weeks gestation in March, 1983.

Past medical history was unremarkable. On her first prenatal visit, blood pressure was 130/108; however subsequent blood pressures were around 120/80. Hemoglobin was 12.3, hematocrit was 38.5, serum creatinine was 0.7, urinary protein was 165 mg in 24 hours, blood type was 0 positive.

The pregnancy progressed uneventfully, and she spontaneously delivered a full term infant with 1 and 5 minute apgars of 9 and 9. The infant has remained in good health.

Case 4: T.B. is a 27-year-old white female G2P0100 with a known history of APKD. Her LMP was 7-13-81 and she was approximately 12 weeks gestation at the time of her first prenatal visit. Other than an episode of cystitis, she had been asymptomatic from her polycystic kidney disease.

Her mother also had APKD. Her father had heart disease, and her aunt and maternal grandmother had diabetes mellitus. The patient had no previous surgery or serious illnesses. Her first pregnancy had ended in the delivery of a stillborn male fetus at 28 weeks gestation, probably due to a cord accident. The fetus weighed 415 g and was macerated, but had no gross anomalies.

On initial prenatal visit, the patient's blood pressure was 114/80. She weighed 119 lbs. and was 5'4". An ultrasound examination at 30 weeks was consistent with dates. Aside from monilial vaginitis at 24 weeks, the pregnancy was uneventful until 36 weeks when the blood pressure was recorded as 140/90 with trace proteinuria. Weekly nonstress tests were reactive, but the patient's blood pressure remained elevated to 150/92 with + proteinuria and a 5 lb. weight gain in one week. Clotting studies and liver function tests were within normal limits. The BUN was 9, serum creatinine 0.7, hemoglobin 12, hematocrit 35.8. Her cervix was long and closed with the vertex presenting at −3 station.

Because of worsening hypertension unresponsive to bedrest and an uninducible cervix, the patient underwent a primary low transverse uterine segment cesarean section at 39 weeks gestation and delivered a female infant with one and five minute apgar scores of 9 and 9. Both mother and infant did well and were discharged on the fifth postoperative day.

Discussion

These four cases illustrate three different, yet typical courses of APKD in pregnancy. One patient (case 3) was essentially asymptomatic; one (case 1) had gross hematuria which resolved spontaneously without sequelae, probably due to hemorrhage into a renal cyst; and the other two had hypertension which worsened near term. Of these last two, case 2 showed pre-existing chronic hypertension, and the other (case 4) had a course more consistent with pregnancy induced hypertension. None of the described cases exhibited the fourth frequent complication of APKD in pregnancy—pyelonephritis, which occurs in 10-33 percent of pregnant women with polycystic kidney disease.[4]

As in these four cases, most women with APKD have few serious problems either in achieving or carrying a pregnancy,[5] but the obstetrician must be vigilant in screening for potential complications. During their childbearing years, it is rare for women with APKD to suffer from severe renal compromise; however, pregnancy outcome is poor if the patient is uremic. In these cases, early delivery, as soon as reasonable fetal maturity is attained or when growth retardation or fetal compromise is detected is recommended since, as with all serious renal impairment, fetal loss at term is high.[4]

Enlarging renal cysts and hematuria are common symptoms in patients with APKD. These are usually successfully managed with bedrest and avoidance of trauma; although occasionally hemorrhage can be severe enough to cause obstruction, so that it may be necessary to bypass the obstruction with a ureteral catheter.[3] Excessive pain should alert the clinician to the possibility of a renal calculus. Interestingly, Milutinovic et al.[5] did not find an increased incidence of pyelonephritis in women with APKD, as opposed to matched controls; though pyelonephritis was more likely to recur in subsequent pregnancies in the polycystic kidney disease patients. Because of the serious implications of repeated pyelonephritis on future renal function and because of the predisposition of all pregnant women to urinary tract infections, women with APKD must be carefully screened, up to every week, for infection. Infection must be aggressively treated, especially since antibiotic levels in the cysts are often only 15-25 per cent serum levels.[3]

Hypertension is more frequent among women with APKD than among other gravidas. The incidence of pregnancy induced hypertension, however, is not increased.[5] The pathophysiology of the hypertension in APKD is uncertain. It does not appear to be related to either volume overload or to alterations in the renin-angiotensin systems, but hypertension is often present before the diagnosis of polycystic kidney disease is made.[3] The hypertension usually responds to conventionally antihypertensive medication, and reasonable control can be attained during pregnancy. In patients with pre-existing severe hypertension, however, pregnancy should not be advised.[4]

Liver cysts rarely present a problem either during or after pregnancy. Approximately 5-16 percent of those with APKD do have cerebral artery aneurysms. These seldom rupture if they are less than 1 cm. in diameter, though they have been implicated in the death of 15 percent of patients with APKD.[3] When it is known that a pregnant women has a significant cerebral aneurysm, it is probably advisable to deliver by elective cesarean section or to give epidural anesthesia and outlet forceps to minimize Valsalva maneuvers.[4]

Although most women with APKD have little problem during pregnancy, especially if they are in good health at the outset of the pregnancy, it must be remembered the APKD is an autosomal dominant, genetically transmitted disease. Therefore the fetus has a 50 percent chance of developing the disease. Genetic counselling is crucial for women and men with APKD, so they are aware of the risk to their offspring. The course of the disease in a family tends to be similar, so if family members have few symptoms until late in life, the prospective parents can be reassured that, most likely, they and their children will be similarly free of symptoms. However, there have been numerous exceptions to this tendency.[3,6]

APKD has been diagnosed antenatally by ultrasound as early as 30 weeks gestation in several instances,[7,8] but often cysts are not apparent until the third or fourth decade of life, so prenatal screening is not uniformly helpful. APKD must be distinguished from infantile polycystic kidney disease which is autosomal recessive and results in early death of the infant due to renal failure and pulmonary hypoplasia.[9]

Conclusions

Adult polycystic kidney disease is a relatively common inherited disorder, but fortunately most of its serious complications are not manifest until well after childbearing has been completed. Unless women with APKD have severe hypertension or renal failure, they usually have few difficulties with pregnancy. There is, however, and increased incidence of hypertension during pregnancy, but the occurrence of pregnancy induced hypertension does not appear to be increased. Similarly, the course of renal disease is not affected by pregnancy.

However, APKD is genetically transmitted as an autosomal dominant trait. Fifty percent of offspring will be affected. There is currently no reliable method to distinguish between affected and unaffected fetuses, and even many women are unaware that they have the disease when they are of childbearing age. It is essential that parents be aware of the risk to their children and, until a reliable antenatal screening test has been developed, perhaps serious consideration should be given to limiting family size in affected families.

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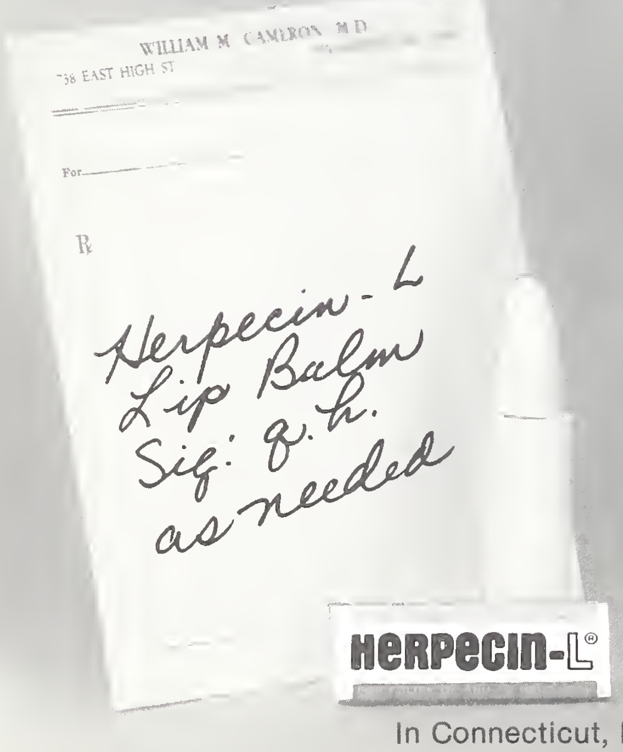
Dx: recurrent herpes labialis



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Important Advances in Clinical Medicine

Epitomes of Progress—Chest Diseases

The Scientific Board of the California Medical Association presents the following inventory of items of progress in chest diseases. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in chest diseases that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Chest Diseases of the California Medical Association and the summaries were prepared under its direction.

Use of Anticholinergic Drugs for Asthma

Natural anticholinergic alkaloids, such as stramonium and atropine, antedate the use of adrenergic compounds as therapeutic bronchodilators for asthma, but were supplanted by the latter in the early 1900s because of problems with dosage and unwanted side effects. Recently, interest in anticholinergic bronchodilators has been rekindled because of a greater understanding of the role of cholinergic influences in asthma and the pharmaceutical development of new atropine derivatives with fewer side effects. These newer agents include the quaternary ammonium compounds, ipratropium bromide and atropine methonitrate. Unlike atropine, these derivatives are poorly absorbed systemically from the respiratory and gastrointestinal tracts and do not penetrate the blood-brain barrier. Consequently, they are longer acting and have a much wider safety margin, being devoid of such systemic atropinic side effects as blurred vision, urinary hesitancy, tachycardia, skin dryness and flushing and mental changes, although some dryness of the mouth can occur due to a local antimuscarinic effect on salivary flow. Whereas atropine decreases mucus secretion, mucociliary transport and ion and water flux across the tracheobronchial epithelium, it does not appear to affect sputum volume or viscosity. Ipratropium has no demonstrable effect on mucus production or clearance. Currently, atropine sulfate is the only anticholinergic compound available for use as a bronchodilator in the United States. It has not been approved by the Food and Drug Administration for such use, however, and requires a compressed-gas-driven nebulizer for delivery. Ipratropium bromide (Atrovent) should be available shortly in the United States as a metered-dose inhaler. Atropine methonitrate is currently under investigation.

In patients with stable asthma, ipratropium is maximal metered doses (40 to 80 μg) is equivalent in bronchodilator effectiveness to inhaled atropine (2 mg), but both are generally less effective bronchodilators than the newer β-adrenergic agents. The combined use, however, of an anticholinergic and a β-agonist can produce greater and more prolonged bronchodilation than either agent alone. Moreover, some patients with asthma who show little bronchodilator response to β-adrenergic compounds respond well to anticholinergic agents. Compared with β-agonists, anticholinergics have a slightly slower onset of bronchodilation (within minutes), a much slower rise to peak action (60 minutes or more) and a comparable duration of effect (up to six hours). The anticholinergic bronchodilators, while fully protective against methacholine-induced bronchospasm, are less effective than β-agonists in protecting against bronchoconstriction produced by histamine, antigen or cold air hyperventilation. On the other hand, anticholinergic agents may have advantages over β-agonists in asthma provoked by psychogenic factors or the inadvertent use of β-adrenergic blocking drugs.

Anticholinergic agents should be considered as second-line bronchodilators for patients with asthma who have symptoms that are not satisfactorily controlled by β-agonist and theophylline compounds or who have annoy-

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ing side effects from conventional bronchodilators. An additional indication may be massive bronchorrhea. Although the role of anticholinergic drugs in status asthmaticus requires further study, inhaled atropine can be beneficial in patients with severe acute asthma who have not responded well to conventional therapy. The initial dosage for adults should be 1 mg or 2 to 3 ml of saline via a power-driven nebulizer every six hours or four times a day. If well tolerated, the dose can be increased, if necessary, up to a maximum of 2.5 mg (optimal dose, 0.025 mg per kg of body weight in adults, 0.05 mg per kg in children). Contraindications include glaucoma and prostatic hypertrophy. When commercially available, ipratropium can be administered more conveniently for long-term use from a pressurized nebulizer in a metered dose of 40 μg (two actuations) four times a day.

In chronic bronchitis and emphysema, unlike asthma, anticholinergic compounds appear to be more effective bronchodilators than β-agonists. In chronic obstructive pulmonary disease, therefore, ipratropium eventually may be considered a first-line bronchodilator agent, possibly in combination with theophylline, a β-agonist or both.

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Clinical Utility of Bronchoalveolar Lavage

Bronchoalveolar lavage (BAL) is a powerful addition to the repertoire of fiber-optic bronchoscopy techniques. In contrast to traditional "bronchial washing," which obtains specimens only from the proximal airways, BAL allows direct sampling of alveolar contents by simple irrigation of the lung with a bronchoscope wedged in a segmental or subsegmental bronchus. As a clinical diagnostic tool, it has proved far more useful than initially suspected. Its greatest success has come in the diagnosis of pulmonary infiltrates in the setting of immunocompromised patients, especially those with the acquired immunodeficiency syndrome. It has proved nearly 100% effective in the diagnosis of *Pneumocystis carinii* pneumonia, a primarily alveolar infection, and has been quite helpful in diagnosing other infections as well, such as *Mycobacterium avium*-intracellulare and cytomegalovirus. There are scattered reports of its efficacy in the diagnosis of noninfectious problems as well—such as adenocarcinoma, pulmonary hemorrhage, asbestosis and alveolar proteinosis. Therefore, though its sensitivity and specificity have not been completely elucidated, BAL is currently indicated in any patient undergoing fiber-optic bronchoscopy for an undiagnosed mass or infiltrate. It will add substantially to the yield of traditional bronchoscopic techniques—that is, bronchial brushing and transbronchial biopsy—with almost no increase in time, expense or morbidity of the procedure.

Bronchoalveolar lavage was initially described for clinical use in the staging of disease activity in patients with interstitial lung diseases. Comparison between specimens from lavage and histologic specimens from simultaneous open-lung biopsy has shown remarkably good correlation in the distribution of cell types—cell differential—between the two procedures. BAL also allows recovery of specific lung proteins such as fibronectin, collagenase and leukotrienes that may provide insight into pathogenetic mechanisms of a variety of diseases, especially asthma and the interstitial lung diseases (sarcoidosis, chronic hypersensitivity pneumonitis and idiopathic pulmonary fibrosis). Patients with active inflammation in the lung due to idiopathic pulmonary fibrosis were reported to have an increased percentage of polymorphonuclear leukocytes in their lavage fluid, whereas those with sarcoidosis or chronic hypersensitivity pneumonitis were said to have increased lymphocytes. Unfortunately, this simple separation of disease types by cell differentials has not proved satisfactory. There is considerable variability in the determination of simple cell differentials among different laboratories. Futhermore, the findings on cell differentials have not proved reliable for predicting either disease activity or responsiveness to therapy, and more reliable markers of disease activity are not yet available. Therefore, as far as the staging of interstitial lung disease is concerned, at the present time BAL should be regarded as strictly a research tool with great promise for the future.

Except for transient low-grade fever, modest hypoxemia and patchy pulmonary infiltrates in the area of lavage, the procedure has proved itself remarkably free of serious complications. It can even be done in patients with bleeding diatheses or those being maintained on mechanical ventilation.

In sum, BAL is a surprisingly safe technique that has become a routine part of fiber-optic bronchoscopy carried out for the diagnosis of unexplained pulmonary infiltrates or masses. Its role in the staging of interstitial lung diseases remains to be established but it has already proved itself as a valuable research tool in studying lung inflammation.

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Sarcoidosis and Hypercalcemia

Hypercalcemia and hypercalciuria are frequent complications of sarcoidosis. The estimated incidence of hypercalcemia is about 11%; hypercalciuria, however, is three times more common. These abnormalities of calcium metabolism are due to increased production of calcitriol or 1,25-dihydroxyvitamin D_3 (1,25-[OH] 2-D_3). Serum levels of calcitriol, the active metabolite of vitamin D, are increased in patients with sarcoidosis who have either hypercalcemia or hypercalciuria or both.

In healthy nonpregnant humans, vitamin D is converted by the liver to 25-hydroxyvitamin D, which in turn undergoes hydroxylation in the kidney to form 1,25-hydroxyvitamin D_3 (calcitriol). The production of 1,25-dihydroxyvitamin D_3 is tightly regulated by parathyroid hormone. In patients with sarcoidosis, uncontrolled production of 1,25-dihydroxyvitamin D_3 occurs at extrarenal sites, namely, blood monocytes, alveolar macrophages and tissue granulomas. These patients are unusually sensitive to vitamin D, which in small doses can produce hypercalcemia. The availability of more precursor vitamin D (diet, medicine, sunlight) leads to increased 1,25-dihydroxyvitamin D_3, which in turn promotes intestinal absorption of calcium.

There are many causes of hypercalcemia but the following three are the most common: primary hyperparathyroidism, neoplasm and sarcoidosis. In primary hyperparathyroidism, hypercalcemia is associated with circulating parathyroid hormone levels in the high or high-normal range and elevated urinary secretion of adenosine 3′:5′-cyclic phosphate. A subnormal serum albumin concentration is a key feature of the hypercalcemia due to neoplasm; 1,25-(OH)2-D_3 levels are usually elevated. The serum chloride level is low in some patients with hypercalcemia due to malignancy. In sarcoidosis, hypercalcemia is associated with increased 1,25-(OH)2-D_3 and serum angiotensin-converting enzyme levels; the parathyroid hormone concentration is normal. Thus, the triad of hypercalcemia, elevated serum angiotensin-converting enzyme and increased 1,25-dihydroxyvitamin D_3 strongly favor sarcoidosis as the cause of hypercalcemia.

Once the diagnosis of sarcoidosis is established, the treatment is relatively straightforward. I usually give 20 to 40 mg of prednisone daily in a single dose. For patients with severe hypercalcemia, I prefer a higher dosage—60 to 80 mg—of prednisone a day. The dose is then gradually reduced to a maintenance level of about 10 mg daily. An alternate-day regimen can be used effectively.

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Respiratory Muscle Fatigue

Muscle fatigue is defined as the inability to sustain a required force. The respiratory muscles behave like other skeletal muscles and fatigue develops when they are subjected to excessive loads. Muscle fatigue results from contractile failure within muscle fibers, rather than from impaired neuromuscular transmission or central nervous system fatigue. In addition to the treatment of underlying lung disease, the management of respiratory failure requires that attention be directed to the ventilatory pump itself. Factors that impair muscle contractility must be corrected. These include low cardiac output, acidosis, hypoxemia, hypercapnia and low serum levels of potassium, magnesium and phosphorus. In addition, other methods have been suggested to improve and optimize ventilatory muscle function and may be valuable both in acute conditions and for long-term benefit. These include drugs such as the methylxanthines, ventilatory muscle rest, ventilatory muscle training and nutritional supplementation.

Methylxanthines. Apart from a central stimulant effect, it is now clear that theophylline increases the contractile tension of skeletal muscle. The mechanism may be related to increased calcium release from the sarcoplasmic reticulum. Still controversial is whether the degree of enhanced contractility of the diaphragm is enough to avert respiratory failure or to provide significant clinical improvement in respiratory muscle function.

Ventilatory muscle rest. It has been suggested that chronic fatigue occurs in overloaded ventilatory muscles, leading ultimately to respiratory failure. In nonrespiratory skeletal muscle, recovery from fatigue may take several hours to days, and it has been proposed that resting the ventilatory muscle by the use of controlled mechanical ventilation may be beneficial in improving and strengthening contractility of the inspiratory muscles. Preliminary reports of nocturnal mechanical ventilation in hypercapnic patients with pulmonary and neuromuscular disease suggest that this method may be beneficial, but further control studies are necessary.

Nutrition. Undernutrition and weight loss impair ventilatory muscle strength and endurance, both of which predispose to and perpetuate respiratory failure. Nutritional repletion is important, but it must be remembered that high-calorie diets that contain a large percentage of carbohydrate produce larger quantities of carbon dioxide than do diets containing equicaloric proportions of carbohydrates and fats. Patients with impaired pulmonary function may have difficulty excreting this excess CO_2.

Ventilatory muscle training. Endurance training in general increases skeletal muscle endurance. For ventilatory muscles, there are two methods of training: one is the resistive method, in which the patient breathes at a normal rate through a high respiratory resistance, and the other is the hyperpneic method in which the patient does isocapnic hyperpnea for a prolonged period. Both these methods may improve ventilatory muscle endurance and in some studies have improved overall exercise tolerance in patients with chronic obstructive pulmonary disease. Further work is necessary to delineate the appropriate indications for training versus resting the ventilatory muscle.

The ventilatory pump is as vital to life as the heart. Understanding of the pathogenesis and reversal of ventilatory muscle fatigue is crucial to improving the management of respiratory failure.

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Continuous Monitoring of Mixed Venous Oxygen Saturation

Continuous mixed venous oxygen saturation (Svo_2) monitoring is a research tool that has become commercially available for clinical use. The monitoring system consists of a light source and analyzer connected to fiber-optic bundles embedded within a pulmonary artery catheter. Oxyhemoglobin saturation is measured through the fiber-optic bundles by its predictable effect upon hemoglobin's light absorption.

Svo_2 is determined by the balance between oxygen delivery and oxygen consumption. Oxygen delivery is dependent on both pulmonary and cardiovascular systems, while oxygen consumption is dependent on the clinical situation. With some exceptions, Svo_2 generally functions as an indicator that overall cardiac and pulmonary function is adequate and that tissue oxygen requirements are being met. Although Svo_2 is affected by cardiac output, arterial oxygen saturation, hemoglobin and oxygen consumption, it does not consistently correlate with any of these variables in patients with critical illness such as adult respiratory distress syndrome or acute myocardial infarction.

The clinical value purported for continuous Svo_2 monitoring includes an early warning of change in the oxygen delivery-consumption equilibrium, allowing prompt intervention; a continuous "on line" evaluation of the net results of pulmonary and cardiac function, allowing more rapid changes in the fraction of inspired oxygen and positive end-expiratory pressure; if the Svo_2 remains stable, determination of routine arterial blood gases and hemodynamic indices may be discontinued. Pursuing fluctuations in Svo_2, however, may result in frequent arterial blood gas and hemodynamic measurements of minimal clinical value. Thus, cost saving is equivocal.

The accuracy, reliability and utility of the fiber-optic catheter monitoring system have been shown. It is difficult, however, to determine whether these advantages justify the additional cost and whether they affect patient survival. Widespread clinical use of the techniques should depend on affirmative answers to both issues.

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Nasal Continuous Positive Airway Pressure—Treatment for Obstructive Sleep Apnea

The sleep apnea syndrome has a spectrum that ranges from a subclinical abnormality to a life-threatening disorder. Many therapeutic modalities exist, and physicians should choose the treatment most appropriate for an individual patient. Nasal continuous positive airway pressure (CPAP) has been used since 1981. It represents a significant advance because it is an alternative to tracheostomy in the management of severe obstructive sleep apnea.

Obstructive apnea is produced when subatmospheric intra-airway pressure, generated during inspiration, causes the tongue and soft palate to be drawn against the posterior oropharyngeal wall with resultant airway closure. The application of positive airway pressure through the nares will prevent airway closure and abolish the obstructive apnea syndrome. The mechanism by which CPAP produces this effect is still not completely defined. The simplest explanation is that the continuous positive airway pressure acts as a pneumatic splint and prevents upper airway occlusion by pushing the soft palate and tongue forward and away from the posterior oropharyngeal wall. The mechanism is likely more complex, however, and may involve stimulation of reflexes in the upper airways and the lungs.

While there has been some variation, the CPAP apparatus generally consists of four components: an air compressor or blower provides the source of high air flow; lightweight disposable respiratory tubing carriers air, which may be humidified, to the patient (it is important that dynamic resistance of the tubing be kept low); a mask or other device is used to provide a tight seal about the nares; a positive end-expiratory pressure valve or a mechanical resistance, placed on the exhaust limb of the mask tubing, results in generation of positive pressure. During a nap or nighttime study, positive pressure is adjusted upward until the apneas are eliminated. The level necessary has generally ranged from 3 to 15 cm of water pressure. The major drawback to nasal CPAP is the inconvenience of nightly use of the apparatus, which some patients find cumbersome. It must be strongly emphasized that the key to the successful use of nasal CPAP is patient education and training. Skilled supervision in the initial use of the equipment and follow-up are crucial for patient compliance and success.

While nasal CPAP can be used to treat mild sleep apnea, more commonly it is used in the severe cases. Because obstructive apneas are eliminated immediately with its application, nasal CPAP is an alternative to tracheostomy in life-threatening situations. Nasal CPAP can be used until other therapeutic modalities, such as weight reduction, medications, uvulopalatopharyngoplasty or mandibular osteotomy, have effected their response. Improvement in the quality of sleep and daytime symptoms occurs rapidly after the initiation of nasal CPAP. Polysomnograms show the return of slow-wave sleep (stages III and IV) and disappearance of repeated nocturnal miniarousals. Correction of hypersomnolence enables a patient to function more productively during the day.

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Lung Abscess

With the introduction of antibiotic therapy, the incidence and mortality of lung abscess has decreased dramatically. Therapy has become primarily medical, with surgical procedures required only in rare instances. In the past decade, it became clear that anaerobic organisms are the cause of most cases of lung abscesses, particularly those that are community-acquired.

More recently, it has become apparent that the etiology of lung abscess has continued to change, with an increasing incidence of hospital-acquired (nosocomial) infections due to Gram-negative aerobic bacilli and staphylococci and opportunistic infections in immunocompromised patients. Opportunistic organisms particularly likely to cause lung abscess include atypical mycobacteria, *Nocardia, Legionella* species, *Candida* species, *Aspergillus* species and the Phycomycetes. It is critically important in such cases to determine the precise nature of the infecting organisms so that appropriate therapy can be given. As sputum cultures are notoriously unreliable in this regard, other techniques, including transtracheal aspiration, collecting bronchoscopic material with protected catheters, transthoracic needle aspirates and cultures of empyema fluid (when present) are often indicated in compromised hosts or inpatients.

Prolonged high-dose penicillin therapy is still the standard therapy for community-acquired lung abscesses, which are usually due to anaerobic organisms. Recent reports, however, of penicillin-resistant anaerobic organisms and treatment failures with penicillin administration have led to suggestions that clindamycin may well be the antibiotic of choice, particularly if *Bacteroides* species is identified, if penicillin allergy is suspected, if a patient fails to respond to penicillin therapy and perhaps if a patient is seriously ill without any of the aforementioned factors being present. Chest physiotherapy may be beneficial in many cases as an adjust to antibiotic therapy, and the use of bronchoscopy to rule out an organic endobronchial obstruction and to improve drainage is still advocated by many, although probably not required as a routine measure. Abscess drainage may be improved by passing a balloon-tipped catheter through the bronchoscope to permit lavage of the affected area.

Surgical excision of chronic abscess cavities, commonly done in the preantibiotic era, is now rarely indicated. Recent reports of successful percutaneous drainage, either by pneumonotomy or tube thoracostomy, or of chronic lung abscesses that have failed to close after appropriate antibiotic therapy, suggest that such modalities may play an increasingly important role, particularly in critically ill patients.

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Air Travel and Patients With Pulmonary Problems

Flying aboard commercial jet aircraft exposes passengers to many environmental stresses, including altitude-induced hypoxia and decreased atmospheric pressure. These stresses are ameliorated by cabin pressurization (to between 5,000 and 8,000 ft) and are well tolerated by most persons, including those with mild cardiorespiratory disorders. Patients with more severe chronic pulmonary conditions and hypoxemia (arterial oxygen tension [Pa_{O_2}] of less than 70 mm of mercury) at ground level, however, are potentially vulnerable to significant hypoxia-related cardiopulmonary or neurologic (or both) dysfunction and symptoms even at moderately high altitudes. In these persons the risk of clinical sequelae is increased by smoking (with increased carboxyhemoglobinemia), alcohol ingestion, exercise, sleep and the drying effects of the cabin environment on respiratory secretions.

Preflight evaluation of patients with chronic lung disease should rely on both objective test results and clinical judgment. Patients with resting or exertional dyspnea, cyanosis, cor pulmonale, bullous lung disease, a vital capacity of less than 50% of predicted, a maximum voluntary ventilation of less than 40 liters per minute, hypercapnia or a Pa_{O_2} (measured while a patient is breath-ing room air) of less than 50 mm of mercury are considered at high risk for altitude-related morbidity. An advising physician must also consider coexisting anemia, hemoglobinopathy and disorders of the cardiovascular and central nervous systems that may be exacerbated in a hypoxic environment. The findings of a routine history, physical examination, hemogram, serum electrolytes, electrocardiogram, chest radiograph, spirometry and exercise tests may indicate serious abnormalities (at ground level) but these tests are limited in predicting altitude tolerance or Pa_{O_2}. The most practical and accurate discriminator of altitude Pa_{O_2} is the Pa_{O_2} at ground level. A formula has been developed for predicting altitude Pa_{O_2} in normocapnic patients with chronic obstructive pulmonary disease at elevations between 5,000 and 10,000 ft:

$$\text{altitude } Pa_{O_2} = 22.8 - 2.74x + 0.68y$$

where x = anticipated (cabin) altitude in thousands of feet and y = room-air resting Pa_{O_2} in mm of mercury at ground level. Useful information regarding symptomatic, cardiovascular and neuropsychological responses to acute hypoxia (the major threat of altitude) may be obtained directly with a hypoxia-altitude simulation test that may be done in many pulmonary function laboratories. This stress test involves the breathing of hypoxic gas mixtures that simulate the inspired oxygen concentration of one or more anticipated altitudes and the monitoring of arterial oxygenation (by oximetry or an indwelling arterial catheter), electrocardiogram and symptoms, with or without light exercise or supplemental oxygen. An altitude Pa_{O_2} of less than 50 mm of mercury, oxygen saturation of less than 85% (or higher thresholds, depending on clinical judgment) or the presence of adverse cardiac or other responses signal the need for possibly corrective intervention, such as supplemental oxygen, drug therapy or smoking cessation, or advice to forego air travel.

A patient with pulmonary problems who is considered a stable candidate for commercial air travel may require further assistance from his or her physician, oxygen vendor and airline(s), depending on the patient's fitness and respiratory status, need for supplemental oxygen and flight itinerary. The physician may be asked to prescribe oxygen requirements and other special needs. The oxygen vendor may need to provide services at stopovers, the final destination and for the return flight. American carriers cannot legally allow passengers to use their personal oxygen units aboard aircraft. Most major airlines in the United States will provide inflight oxygen with advance notice. Unfortunately, airline policies differ widely regarding oxygen capabilities and inflight use of respiratory equipment. These issues, if applicable, need to be inquired about in detail. Further advice and assistance can be obtained from local pulmonary rehabilitation programs and the California Thoracic Society, American Lung Association of California, 424 Pendleton Way, Oakland, CA 94621.

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Noninvasive Determinations of Arterial Oxygenation and CO_2 Tension

Most arterial blood analysis is done to evaluate oxygenation (partial pressure of arterial oxygen [Pa_{O_2}]) and adequacy of ventilation (arterial carbon dioxide tension [Pa_{CO_2}]). It is now technically possible to do these measurements noninvasively. Noninvasive determination of arterial O_2 saturation by transmitting two infrared wavelengths through the ear capillaries was developed in 1935 but was clinically unacceptable because of difficulties in calibration and inaccuracy in the clinical setting. Improved technology in the 1970s, using two to eight wavelengths, coupled with analysis of the pulse of arterial blood in the ear heated to 39 °C, allowed for simplified calibration and clinically useful ear oximetry. Simultaneously, neonatologists found that the blood O_2 electrode applied to the skin heated to 44 °C could give accurate estimates of Pao_2 when blood flow to the skin was adequate. Such measurements have largely replaced arterial blood gas analysis in neonatal intensive care units. In adults, the thickened skin (physiologic if not sociologic) made transcutaneous O_2 tension ($Ptco_2$) less reliable.

Similarly, the transcutaneous CO_2 pressure can be measured using either infrared transmission or the blood CO_2 electrode. Accuracy still depends on adequate blood flow to skin but less so than $Ptco_2$ since a continuous flux of CO_2 through the skin is not needed. CO_2 can also be measured in the exhaled air by infrared analyzers or mass spectrometry. The end-tidal CO_2 pressure ($Petco_2$) approximates $Paco_2$, and rebreathing methods can give better approximation of the mixed venous CO_2 pressure ($Pvco_2$).

These noninvasive methods are being increasingly applied clinically in the 1980s. As technology improves and becomes more familiar, their use can be expected to increase and replace arterial blood gas determinations in adult patients, as it already has in neonates. Several well-established applications for ear oximetry are as follows: to monitor for sleep apnea and hypoxemia during sleep studies; to adjust the amount of inspired O_2 at the bedside to achieve the desired O_2 saturation (usually more than 90% or a Pao_2 of more than 60 torr); to monitor oxygenation during exercise studies, and to monitor oxygenation in critically ill patients in intensive care units. These measurements should be verified by an initial simultaneous arterial blood analysis, particularly in a critical care setting or when the data are not consistent with the clinical assessment. Repeated arterial punctures to monitor oxygenation, however, are clearly no longer necessary or desirable.

Transcutaneous O_2 monitoring may also be used in the above settings but is more time-consuming to set up, requires higher temperatures (44 °C), leaving a burn on the skin and therefore needs to be moved every three to four hours, and is more critically dependent on skin blood flow for accuracy.

Noninvasive monitoring of CO_2 is less common and usually applied to critically ill patients where ventilatory failure is imminent or present and endotracheal intubation and mechanical ventilation are indicated. A single skin electrode is now available to monitor both $Ptco_2$ and $Ptcco_2$. A single infrared unit can be used to alternately monitor both airway CO_2 ($Petco_2$) and $Ptcco_2$. The $Petco_2$ underestimates the $Paco_2$, and $Ptcco_2$ tends to overestimate the $Paco_2$. Monitoring both $Petco_2$ and $Ptcco_2$ can provide a bracket to estimate $Paco_2$. Changes in $Petco_2$ or $Ptcco_2$ indicate either changes in $Paco_2$ or in the gradient between $Paco_2$ and $Petco_2$. The $Paco_2$-$Petco_2$ gradient increases with abnormalities in ventilation (low tidal volume or maldistribution of ventilation), while the $Paco_2$-$Ptcco_2$ gradients increase when skin blood flow decreases or increases $Pvco_2$ due to metabolic changes. Therefore, a change in a noninvasive CO_2 measurement indicates either true $Paco_2$ changes, not uncommon in mechanically ventilated patients, or possibly a clinically significant pathologic change in ventilation, blood flow or metabolism. "Smart" alarm systems capable of analyzing such complex physiologic data to differentiate artifact from actual changes are technically possible, but the utility or necessity in a patient with critical ventilatory and circulatory problems is yet to be determined. For now, successful use of noninvasive CO_2 measurement depends on a "smart" and experienced critical care team.

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Home Oxygen Therapy

Home oxygen therapy is indicated to correct hypoxemia and prevent the adverse cellular effects of hypoxia reflected in abnormalities of brain, heart and lung function. Hypoxemia is assessed by clinically evaluating a patient and by directly measuring arterial blood oxygen tension and saturation.

The management of hypoxemia due to chronic lung disease is the principal clinical indication for home oxygen therapy. Ongoing oxygen therapy should be prescribed for those patients who, after a month of optimal medical management, show a resting, nonrecumbent arterial oxygen tension of less than 55 mm of mercury or an arterial oxygen saturation of less than 85%. Patients with evidence of pulmonary hypertension, impaired mentation or erythocytosis qualify for home oxygen therapy if their arterial oxygen tension is less than 60 mm of mercury.

The National Institutes of Health Nocturnal Oxygen Therapy Trial showed the superiority of continuous over nocturnal oxygen therapy in the treatment of hypoxemia due to chronic obstructive pulmonary disease.

When hypoxemia occurs only during sleep, or when supine, and if the arterial oxygen tension falls to less than 55 mm of mercury or the oxygen saturation to less than 85%, oxygen therapy during sleep, or when supine, is indicated.

Oxygen therapy during exercise may be prescribed if the arterial oxygen falls below 55 mm of mercury or saturation falls below 85% during exercise, or if laboratory exercise studies show that oxygen improves exercise performance.

An oxygen prescription should designate the equipment needed—that is, stationary or portable oxygen supply, regulator and cannula or mask. In general, humidification is not required with low-flow oxygen. The prescription should indicate the flow rate, diagnosis, length of time oxygen is to be required, prognosis and a recent blood gas value. The flow rate prescribed is that which will alleviate hypoxemia. Flow rates between 1 and 5 liters per minute are generally prescribed. Flows above 5 liters per minute are impractical; the use of newer oxygen-sparing cannulas, however, may permit effective oxygen therapy for patients requiring a high oxygen concentration. Oxygen may be supplied in compressed cylinders, liquid reservoirs or oxygen concentrators. Cost and convenience factors generally dictate the type of oxygen supplied.

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Passive Smoking and Health

Passive smoking refers to the involuntary exposure of nonsmokers to tobacco combustion products released from a burning cigarette and exhaled by an active smoker. In enclosed spaces, tobacco smoking increases the concentration of gases and respirable particulate matter. Passive smoking appears to involve inhalation of most tobacco combustion byproducts. For example, cotinine, the major metabolite of nicotine, has been detected in the plasma, urine and saliva of nonsmokers exposed to tobacco smoke. Passive exposure to tobacco smoke has been linked primarily to respiratory effects.

Upper airway problems associated with passive smoking include irritation, persistent middle-ear effusions in children and an increased frequency of tonsillectomy and adenoidectomy in children. Epidemiologic investigations have linked passive smoking in children to increased occurences of lower respiratory tract infections; increased cough, phlegm and wheeze, and to reduced lung function. At present the evidence is most convincing for lower respiratory tract infections during infancy. The results of longitudinal investigations have shown an increased risk of bronchitis and pneumonia during the first year of life for children with smoking parents.

Investigations in adults have focused on the effects of passive smoking on respiratory symptoms and lung function and on lung cancer risk. For respiratory symptoms, the available data do not show a consistent pattern. Reduced flow rates at low lung volumes, suggestive of small airways abnormalities, have been associated with passive smoking in two studies. While patients with chronic cardiac and pulmonary diseases may be postulated to be particularly susceptible to the effects of passive smoking, little relevant data are available. Because of methodologic constraints, particularly in accurately quantifying exposure, studies of passive smoking and lung cancer offer conflicting results. Passive smoking is a biologically plausible risk factor for lung cancer, however.

In the United States, about 54 million adults are currently smoking. The resulting high prevalence of exposed nonsmokers makes passive smoking an important public health problem.

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Acquired Immunodeficiency Syndrome—The Diagnosis of *Pneumocystis carinii* Pneumonia

There is no laboratory test for diagnosing the acquired immunodeficiency syndrome (AIDS). The manifestation of immune deficiency implied by the presence of opportunistic infection, tumors and other processes heralds the presence of this syndrome and related manifestations, known collectively as AIDS-related complex or ARC. The use and diagnostic significance of human T-lymphotrophic virus type III in the diagnosis of AIDS are controversial and uncertain at this time.

Pneumocystis carinii pneumonia afflicts 60% to 85% of AIDS patients, half of whom will have recurrence of the illness within 12 months. The patients who are diagnosed early with mild hypoxia are more likely to survive an episode of *P carinii* pneumonia than patients in whom a diagnosis is delayed.

Among patients with AIDS, *P carinii* pneumonia often presents insidiously over a period of one to two months. Cough and dyspnea in patients at risk for AIDS should always suggest the presence of *P carinii* pneumonia. Patients at risk for AIDS include homosexuals and heterosexuals in whom there is an appropriate exposure history, intravenous drug abusers and patients who have received blood or blood products during the previous five years. The history and physical examination may imply the presence of immune suppression. An oropharyngeal examination may reveal thrush, oral Kaposi's sarcoma or hairy leukoplakia. Cutaneous findings include Kaposi's sarcoma, a new onset of seborrheic dermatitis or herpetic anogenital infection. An eye examination may show conjunctival Kaposi's sarcoma as well as cotton-wool exudates and findings consistent with cytomegalovirus retinitis. Additional findings labeled ARC include diffuse adenopathy, prolonged unexplained fever, diarrhea and weight loss or "wasting." Of note, two thirds of patients with *P carinii* pneumonia have normal chest auscultatory findings.

The chest radiograph is helpful if there is a diffuse ground-glass infiltrate, but focal infiltrates have also been noted. Furthermore, the chest radiograph is normal in the presence of AIDS-related *P carinii* pneumonia in 8% to 25% of the cases. Routine laboratory findings include anemia (80%), lymphopenia (42%), thrombocytopenia (6%), increased lactate dehydrogenase (78%) and an elevated erythrocyte sedimentation rate (100%). Arterial blood gas determinations obtained at rest and with the patient breathing room air classically show hypoxia and hypocarbia but may be normal in 10% to 30% of patients. Among patients at risk for AIDS who possibly have *P carinii* pneumonia with normal or borderline abnormalities of the chest radiograph or arterial blood gases, the pneumonia can be detected by a diffusely positive gallium lung scan. Similarly, in patients with subradiographic evidence of the disease, pulmonary function tests show an increased flow rate as measured by an increased forced expired volume in one second expressed as a percent of the forced vital capacity (increased FEV_1%), as well as a decreased diffusing capacity for carbon monoxide.

The diagnosis of *P carinii* pneumonia requires appropriate staining of bronchoscopically derived lung tissue or secretions. Flexible fiber-optic bronchoscopy using both transbronchial biopsy and lavage approaches 100% sensitivity. In our recent series, the lavage alone detected the presence of *P carinii* pneumonia in 34 of 35 cases (97%). Recently, we found that an induced sputum specimen shows the presence of *P carinii* pneumonia in 50% to 60% of patients with the pneumonia.

Our present diagnostic approach in patients suspected of having *P carinii* pneumonia is to attempt to induce a sputum specimen as the first step. Following negative results of sputum induction, we do lavage with the fiber-optic bronchoscope and, more recently, a newly designed disposable catheter and fiber-optic stylet (Microvasive, Inc, Boston). If the results of a lavage are negative and if the patient is still felt to have *P carinii* pneumonia, bronchoscopy is done with transbronchial biopsy and repeat lavage. Using this approach, we have virtually never resorted to an open-lung biopsy in patients with possible *P carinii* pneumonia in the context of AIDS.

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Bronchoscopic Needle Aspiration

Bronchoscopic needle aspiration is a relatively new technique that has expanded the use of fiber-optic bronchoscopy in the diagnosis and staging of lung cancer. The aspirating device consists of a needle attached to tubing, often housed within an outer protective sheath. Lesions that can be seen through the bronchoscope can be aspirated directly. Otherwise, the needle is positioned with fluoroscopic guidance.

Mediastinal and hilar nodes, which were previously inaccessible to bronchoscopic sampling, can be aspirated with yields up to 90% in lesions that are visible on the chest roentgenogram. The technique is also useful in detecting cancer in subcarinal nodes that are not visible on the chest roentgenogram. The yield is highest when the carina appears wide at bronchoscopy (40%) or the primary tumor is located in a visible bronchus (25%).

Bronchoscopic needle aspiration can also increase the yield of bronchoscopy in the diagnosis of cancer in central bronchi and peripheral masses. Tumors that spread in the submucosal or adventitial layers of bronchi are often difficult to diagnose by forceps biopsy. Needle aspiration of such lesions can increase the yield from 55% with forceps biopsy to 90% with both techniques. In peripheral masses, needle aspiration also increases the yield over transbronchial biopsy alone.

Bronchoscopic needle aspiration appears to be a safe technique in experienced hands. Pneumothorax is rare and significant bleeding has not been reported. Needle aspiration tends to produce less bleeding than forceps biopsy and may be the procedure of choice for friable lesions. The false-positive rate also appears to be low. No false-positive results occurred in three large studies of transcarinal aspirates.

Thus, bronchoscopic needle aspiration can increase the yield without increasing the risk of fiber-optic bronchoscopy in both the diagnosis and staging of lung cancer. Its use in staging can spare patients with inoperable disease the morbidity and expense of surgical staging. Its role in the diagnosis of nonmalignant disease needs further study.

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Nutrition and Ventilator-Dependent Patients

Recent observations in ventilator-dependent patients who are receiving nutritional support have underscored the interdependence of the pulmonary system and tissue metabolism. Metabolism by body tissues may stress the function of a diseased pulmonary system that is already requiring support. Nutrient type and amount will drive tissue carbon dioxide production just as fever and activity increase it. In a patient with limited alveolar ventilation, this increase in CO_2 production has led to respiratory acidosis and an inability to wean from the ventilator.

Because of differing respiratory quotients for various food substrates, carbohydrate calories are potentially more troublesome than fat or protein in this regard. In particular, an excessive intake of carbohydrate that results in fat storage drives the respiratory quotient to greater than unity and increases the likelihood of CO_2 retention.

If caloric need is estimated by indirect calorimetry (oxygen consumption used to measure needs) or an established caloric prediction equation (such as the Harris-Benedict equation) and if glucose administration is below 5 mg per kg body weight per minute, CO_2 retention is unusual. If fat is used to provide some of the daily calories, then glucose administration rarely needs to exceed this limit. In troublesome cases, measuring the CO_2 production and oxygen consumption, paying attention to the respiratory quotient calculation, will help determine an appropriate feeding mixture for a patient.

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Filicide: An Update

ARNOLD A. HEIGER, M.D.

ABSTRACT— Filicide has been with us since the pre-biblical era. It is only in very recent times that it has become a societal problem. The frequency of filicide seems to be increasing disproportionately to the overall rate of homicide in the United States.

The rate at which parents have been killing their children has been increasing despite the fact that overall homicides have been decreasing in the United States. Articles in newspapers and television expose's have dramatized the scandalous and brutal facts concerning the slaughter of children by their parents. Communities are shocked out of their complacency regarding the safety of the children they know. Parent groups are formed to try to understand the problem and to look into possible preventitive measures. Professional expertise is not meeting society's needs in the area of filicide and infanticide.

Historical Background

Infanticide is a chronic threat that many animals and some primates must face.[1] Among some species of monkeys, infants are killed to reduce competition for food or to increase availability of the female by eliminating lactation. Charles Darwin has stated that infanticide has "been probably the most important of all checks on population growth throughout most of human history."

The heinous act of the killing of one's own child, called filicide, has been described in world literature since before the time of the early Roman Empire. Sacrifice of the first-born to the god Chemosh by the Moabites was the accepted procedure in the prebiblical era. In the Old Testament Jephthah (Judges 11:30-40) offered his daughter as a sacrifice. Abraham was ready to sacrifice his son Isaac until he was prevented. Admonitions against this type of sacrifice of one's own children is well portrayed by the line in Exodus 22:29-30 which states that— "You shall give me your firstborn sons...."[2] The Patria Potestas[3] of ancient Rome allowed a father to "sell, abandon, sacrifice, devour, kill, or otherwise dispose of his offspring." An Athenian father could dispose of his child any way he wished before the Amphidroma which usually took place on the fifth day. A Frision (Netherlands) father could dispose of his child legally only before it was fed for the first time.

From the 7th Century BC to the 4th Century BC in Carthage, animals were used for sacrifice by being burned and buried in amphora jars. After the 4th century BC, children were used in place of animals.[4] Almost all of the children sacrificed were less than 3 years old but some were 6-10 years of age.

Incidence

Jason[5] has delineated child homicide (the murder of a person less than 18 years old) into three categories. These include Neonaticide (the murdering of a person less than one week old); Infanticide (the murdering of a person older than one week but younger than one year); and an overall category of filicide (the murder of a person less than 18 years of age by a parent or stepparent). Statistical data are not available in these categories.

In the 1960's in England and Wales,[6] 1/3 of all murders were of children under 16 years of age. Three quarters of these murders were perpertrated by the parent. However, only 15% of the murderers were the fathers. In 1965, in England, a bill was submitted to Parliament which proposed that there be no punishment of the mother accused of killing her child and that there be no publication allowed of the crime.[7] This followed the Infanticide Act of 1922 which stated that infanticide is not murder and the Infanticide Act of 1938 which sought to protect the mother if she were accused of murdering her infant of less than 12 months of age by virtue of her not having recovered from the act of birth or of lactation.[8] Resnick[3] stated that it is rare for a father to commit neonaticide. When fathers do commit neonaticide or filicide they usually receive more severe sentences than do mothers. Mothers are generally hospitalized whereas fathers receive prison sentences.

The incidence of filicide in the United States from 1968 to 1975 has been fairly constant with an average rate of 3.2% per year of all homicides. This accounted for approximately 560 cases of filicide per year during that period of time.[9] The incidence of homicides in the United States reached its peak in 1980 with a total of 23,040 of which 2,829 were of children below the age of 19. Since then it has been decreasing. The overall incidence of child homicides is approximately 12% of all cases. From 1980 to 1983 the number of filicides has been increasing annually despite the fact that the total number of homicides has been declining. During this period of time the percentage rate of filicide has risen from 0.2%-0.4% per year. This is evident as seen in Figure 1.

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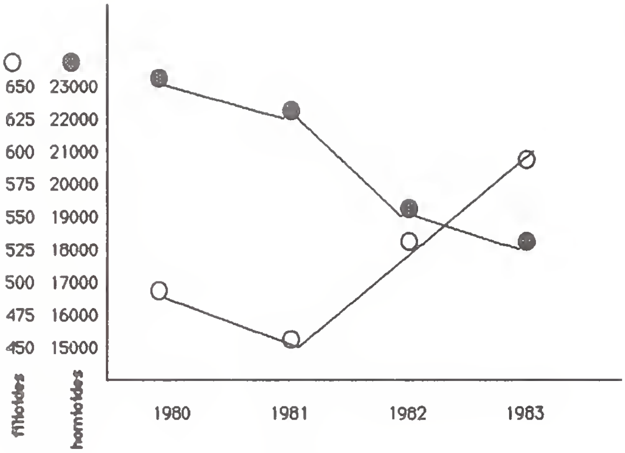

Figure 1

If one plots the number of homicides against the rate of filicides it becomes immediately apparent that there is an inverse ratio between these two parameters; that is to say that the higher the number of homicides the lower the rate of filicides and vica versa. These findings are apparent in Figure 2. Figure 2A shows the relationship between the number of homicides and the number of filicides.

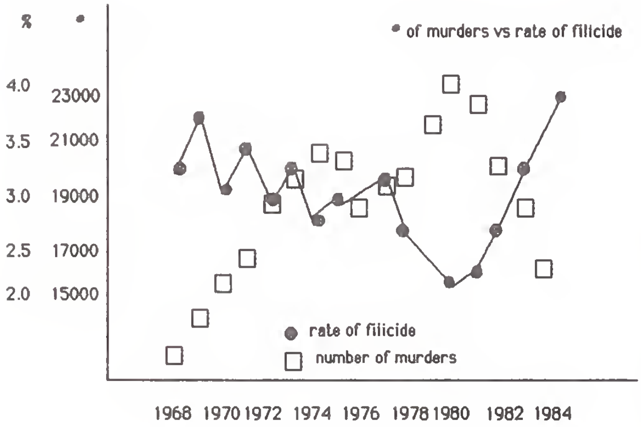

Figure 2

The rate of filicides of male children has always exceeded that of female children in the United States. Sons were victims 1.3 times more than daughters. Since 1977 there has not been one year in which female deaths exceeded male deaths. These statistics include those cases of infanticide as well. In most instances the perpertrator of the homicide was the mother. The numbers of cases of infanticide over the years 1968-80 have remained relatively constant ranging from a low of 150 in 1970 to a high of 210 in 1980.

As mentioned earlier, in the '60's in England only 15% of the filicide cases were caused by the father.[6] For all cases of child homicide 76% of the offenders were mothers while only 19% of the offenders were fathers.[5] When the mother was the perpertrator only 10% of the homicides involved more than one child whereas 17% of the homicides involved more than one victim when the father was the murderer.

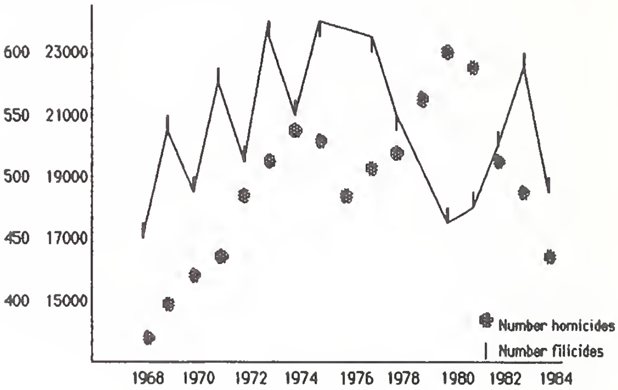

Figure 2A

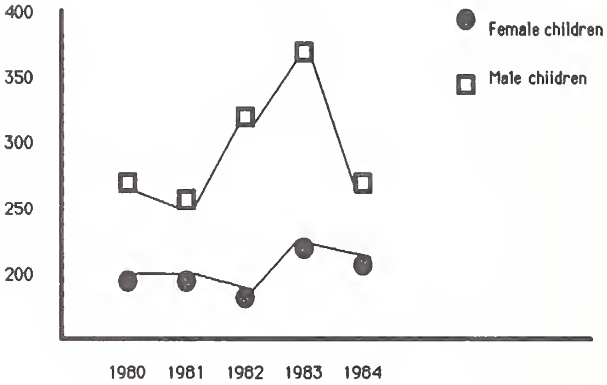

Figure 3

Psychological Theories

Tuteur[10] has quoted other authors as stating that women who did not receive maternal love in their childhood develop less motherliness than others and that filicide and abandonment of children is specifically a female deed. Feinstein[11] treated a group of mothers who stated an impulse to kill their children and found these women had strong feelings of resentment toward their mothers and that they formed relationships with men who were overtly seeking motherly types. The major focus of these women's filicidal tendencies was toward their male child. Feinstein[14] states that the filicidal mothers looked upon their male children as grown men but some used their male children as a repository of the transfer of aggression from their husbands.

Chapman[12] showed that these women are very sensitive to any mention of violence after the onset of their symptoms and they often avoid possible references by not watching TV or reading newspapers. The patients as a rule will discuss their fears with their husbands but not with anyone else. Husin[13] stated that all of the filicidal mothers he studied had major psychiatric illnesses before and at the time of the murder of their children while only 7.7% of abusive mothers are so afflicted. This fact led him to state that any abusive mother who has a major psychiatric disorder must be looked upon as being a potential murderer of her children. He came to the conclusion that mothers who killed their children rarely had a history of abusing them but frequently manifested a history of having been abused themselves by their parents.

Podolsky[14] feels that filicide is a suicidal act as a result of an identification process. "In both schizophrenia and manic depressive psychotics there is a tendency for mothers to project their symptoms onto their children so that the child becomes analagous to an organ in the mother's body." He feels that the act of filicide is very unpredictable but he showed that all mothers had difficulties with their husbands and they displayed a definite coolness for one or both of their parents during their childhood.

Resnick[15] in 1966 listed the following motives for filicide.

a. Altruistic:
  1) associated with suicide i.e "bury us in one box"[10]
  2) to relieve suffering...real or imagined
b. Acute psychotic...in a fit of rage
c. Unwanted child
d. Accidental...during child abuse or deviant sexual pleasure
e. Spouse revenge...as in a story of Medea who killed her children to get at her husband.

In 1973 Scott[6] revised this classification because he felt that the majority of instances of filicide were as a result of a loss of the higher controls of reasoning and self criticism in the parent. The motives for the act of filicide included quarrels, violent rage, suicidal despair, and mercy killings. He recommended a revised classification which included:

a. Elimination of an unwanted child
b. Mercy killing with absence of secondary gain by parent
c. Gross mental pathology of the parent
d. Stimulus arising outside the victim
e. Victim constitutes the stimulus (loss of temper)

Rees[16] stated that crime is the "outward manifestation or sign of some disorder in the personality, however that may have been caused." The fact that social pressures or circumstances may have led to the decision to commit the act of filicide is of no consequence in the opinion of Rees. The psychiatric literature seems to affirm the probable necessity for a psychological set of characteristics in order for any kind of external stimuli to result in an act of filicide. These characteristics have been described previously[13,10] but neither author has made mention of the kind of social pressure that occurs in the Far East...namely the need for a male child or, as in Japan, the act of *oyako shinju* which is still practised. This is the custom of taking of her child's life (or children's lives) at the same time as a mother commits suicide. This is done because there is the belief that it is a greater sin to leave the children behind to be cared for by others than to take the children with oneself.

Since the majority of instances of filicide in the United States involves a mother and a male child, borne out of the fact that 76% of the murderers were women and that male victims exceeded females in all the years for which statistics are available Resnick's theories[15] seem to be the most applicable. The increased divorce rate and estrangement of fathers does not seem to play a role in the frequency of filicide in general. Individual instances of fathers killing themselves along with their children probably occur during an acute psychotic episode and not as a revenge action against their former spouses. Resnick's theory concerning spousal revenge dealt with the mother killing her male child in order to punish her husband. This theory is borne out by the statistically significant preponderance of female murderers over males and the equally significant predominance of victims being males.

In China the restriction to one child per family has led to an increased rate of infanticide of female newborns. The experience in the Far East has historically shown a tendency toward a higher number of female infants being murdered as opposed to the United States which has always shown a greater number of male infants being killed than female. This cultural difference cannot be explained by any of the psychological theories proposed by Rees[16] or Scott.[6] Resnick's classification[3] includes the category of unwanted child which would fill this void. Cultural differences throughout the world seem to be of some importance in explaining reasons for filicide and these same differences must also be considered here in the United States.

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A Primer on Informed Consent for Connecticut Physicians

J. MICHAEL EISNER, JOHN Q. TILSON AND MELINDA A. AGSTEN

SITUATIONS IN WHICH INFORMED CONSENT MUST BE OBTAINED

Except as provided below, a physician must obtain the informed consent of the patient, or of the person giving consent if the patient is unable to consent, before he* performs any invasive procedure or other procedure involving any degree of known risk to the life or well being of the patient. Consent should be obtained, for example, for operations, radiation therapy, and diagnostic imaging involving risk. This requirement to obtain informed consent is incorporated into the Connecticut Public Health Code which provides that in hospitals "except in emergency situations, the responsible physician shall obtain proper informed consent as a prerequisite for any procedure or treatment for which it is appropriate and provide evidence of consent by a form signed by the patient or a written statement on the patient's hospital record." While the Public Health Code requirement is included in the licensing regulations for hospitals and therefore applies to procedures or treatments in a hospital, the regulation is a good statement of the law for procedures or treatments wherever performed.

EXCEPTIONS TO THE REQUIREMENT TO OBTAIN INFORMED CONSENT

(a) Emergencies

The existence of an emergency has been held by the courts to obviate the need for any consent where the patient is unable to consent or is incapable of consenting and the risk of harm caused by delay outweighs the risk of treating without consent. A simple definition of "emergency" would be a situation posing a significant immediate threat to the life or health of the patient. For example, if an unconscious patient were brought to a physician's office or an urgent care center bleeding to death, the physician may provide immediate treatment without consent rather than risking the patient's life in an attempt to obtain substituted consent.

(b) Therapeutic Privilege

A serious problem arises in the situation in which the physician believes that fully informing the patient might be harmful to the patient's health. This gives rise to the so-called "therapeutic privilege" exception. Claiming the privilege, however, entails significant risk on the part of the physician. *The burden of proof to establish the danger of disclosure to the patient's health will be on the non-disclosing physician.* In virtually every case reported in this area, the physician has failed to carry this burden, and has been found liable for failure to obtain informed consent.

THE PHYSICIAN'S RESPONSIBILITY FOR OBTAINING INFORMED CONSENT

It is the physician's responsibility to obtain the informed consent of his patient or, when the patient is not capable of giving his informed consent, the substituted consent of the parent, spouse, guardian or other person acting in place of the patient. The physician who is to perform the surgery or procedure is in the best position to inform the patient, answer the patient's questions, and thereby obtain the consent. It is our strong view that as a general rule it is poor practice to delegate such a task. The physician always will continue to be the person legally responsible for obtaining consent. In our view, the physician who insists on delegating the task should rely upon others to inform the patient only where (1) the procedure is quite routine, (2) the risk is extremely low, (3) he personally is satisified that the task will be performed properly, and (4) the physician always will be available for consultation if the patient has any questions or wishes to speak to the physician for some other reason. The patient always should be informed that the physician is available to answer questions upon request.

Where the physician personally has obtained the consent, there is no reason why a nurse or responsible aide may not be in charge of securing the patient's signature on the consent form, or witnessing the patient's signature. *The form, of course, will be worthless unless the physi-*

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*Any reference in this Primer to males or females, or use of the masculine or feminine gender is intended to include both sexes.

cian has informed the patient and obtained informed consent, and the form accurately reflects this fact.

If consent is not obtained under circumstances where it should have been obtained, the physician will be liable to the patient for harm suffered by the patient even in the absence of any negligence by the physician in performing the procedure. It should be noted, however, that a causal link must be established between the material nondisclosure and the harm suffered by the patient: the patient must establish that disclosure would have resulted in a negative decision. This is a question of fact, but most jurisdictions have held that it must be resolved on an "objective basis," that is, "in terms of what a prudent person in the patient's position would have decided if suitably informed of all perils bearing significance." *Stripek v. Bergamo,* 200 N. J. Super. 620, 491 A.2d 1336, 1346 (1985).

WHAT INFORMATION MUST BE GIVEN BY THE PHYSICIAN TO THE PATIENT OR TO THE PERSON GIVING CONSENT IN ORDER TO OBTAIN A VALID INFORMED CONSENT?

The purpose of consent is not to frighten or bully the patient but to give him enough information to enable him to make an intelligent decision in regard to treatment. A physician is not required to disclose hazards that he cannot reasonably be expected to know about. Nor is he required to disclose hazards which occur so very rarely that no reasonable person would consider them hazards at all, or normal hazards present in any operation or hospitalization. On the other hand, he does have to disclose both known dangers and alternatives, and cannot withhold information merely because it is unpleasant. In our view, if a risk is known to exist, is life threatening or permanently or seriously disabling, and the chances of its occurring are calculable, it always should be revealed to the patient. In one well known case, it was held that the physician was liable for failing to disclose a one per cent risk of paralysis as a result of a laminectomy. In another case, a physician was found liable for failing to disclose a 1 in 2500 risk of perforation of the stomach during a scoping procedure. On the other hand, if a risk appears to be unique and not statistically predictable (*e.g.*, a result which was reported once in the literature but which may never occur again), or is so remote that no reasonable person would consider it a risk at all, then it may not make any sense to require it to be disclosed,* especially if the only likely result of disclosure is to frighten the patient unnecessarily.

In 1983, in the case of *Logan v. Greenwich Hospital Association,* 191 Conn. 282, 465 A. 2d 294, the Connecticut Supreme Court adopted the "patient-oriented" standard of disclosure for informed consent. The patient-oriented standard provides that the patient is entitled to whatever information a reasonable patient could expect to receive in order to make an informed determination as to whether or not he would consent to the procedure.

Accordingly, information provided to the patient should include discussion of benefits, risks, and alternatives. For example:

(1) the physician's diagnosis and prognosis;

(2) the suggested procedure, its purpose, and a brief description of what it involves;

(3) the chances of success or failure of the contemplated procedure;

(4) alternative methods of treatment—even if not preferable—, or the possibility of nontreatment, and the prognosis for such alternatives or nontreatment;

(5) an evaluation of the risks and benefits of the contemplated procedure.

Additionally, the patient always should be advised that the physician is available to answer any questions which the patient might wish to ask. Throughout the course of informing the patient, the physician should strive to use language which the patient understands and should be persuaded that the patient is satisfied that his questions have been answered.

If the patient tells the physician that he does not wish to be informed (*e.g.*, does not wish to hear what might happen to him if the procedure is not performed or does not wish to hear details of known risks associated with the procedure), it is permissible for the patient to delegate the consent decision to the physician. Under such circumstances, however, it is our strong suggestion that the physician attempt to inform the patient. If the patient obstinately insists on not hearing anything but instead wishes to place his fate in the hands of the physician, the physician should carefully note in the chart that the patient was insistent on not being informed and on permitting the physician to make the decision for him.

In summary, the physician is not required to give a course in medicine, but he should be sure that the patient understands what he is saying and is willing to undergo the procedure in spite of the risks.

SUBSTITUTED CONSENT

If a patient is unable to consent because of his physical or mental condition, then substituted consent may be obtained from a close relative. There is no legal requirement that a conservator of the person be appointed. *Cf. Foody v. Manchester Memorial Hospital,* 40 Conn. Sup. 127, 140 (1984).

There is no Connecticut law as to the order in which relatives have the right to consent. However, it may be helpful to follow the formula set forth in the Anatomical Donations Act, (Section 19a-273(b) of the Connecticut General Statutes) which lists the order of consent as follows:

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*In one case, however, a court held that even a remote risk might have to be disclosed if the physician knows that the particular patient would consider the risk to be of significance.

(1) spouse;

(2) adult son or daughter;

(3) parent;

(4) adult brother or sister.

Persons suffering from mental illness who are nevertheless capable of being informed and granting consent to medical or surgical procedures may consent or refuse to consent to medical and surgical treatment. Stated another way, there is no presumption that just because a person is mentally ill he cannot give informed consent. A determination must be made in each case as to whether the mentally ill person is capable in fact of informed consent. Even when hospitalized, mentally ill persons generally retain these rights, although there are some special statutory rules for involuntary mental patients. (*See* Sections 17-206b and 17-206d of the General Statutes.)

In some cases, the incapable person will have been found legally incapable by a probate court, which will have appointed a conservator. If a conservator of the person has been appointed by the probate court, the conservator has the legal power to give consent for medical care and the conservator should give the informed consent. (*See* Section 45-75a of the General Statutes). Caution should be exercised to make certain that the conservator is of the *person* and is not merely of the estate; a conservator of the estate by law has power over property rights but does not have power over medical decisions.

Some states permit an individual (principal) while competent to execute a power of attorney which authorizes another named individual (agent) to make health care decisions for the principal if he cannot speak for himself. Existing Connecticut law does not provide for such a "durable" power of attorney, and a physician should not rely on such a document to take a substituted consent. The physician may, however, consider the existence of the document as one of the factors in determining who should be asked to give substituted consent for an incapable patient.

Finally it always should be kept in mind that the person who is to provide substituted consent on behalf of the patient is to be as fully informed as the patient would have been if capable of giving consent.

MINORS

A "minor" is defined by Section 1-1d of the Connecticut General Statutes as "a person under the age of eighteen . . . . " As a general rule, consent should be obtained from a parent or court-appointed guardian of a minor. Under the circumstances discussed below, however, consent may be obtained from a minor without parental consent (or consent from a court-appointed guardian or other person acting *in loco parentis*).

(a) *Consent to treatment for children of minors.* Section 19a-285 of the Connecticut General Statutes provides that "[a]ny minor who has been married or who has borne a child may give effective consent to medical, dental, health and hospital services for his or her child."

(b) *Venereal disease.* Section 19a-216 of the Connecticut General Statutes permits treatment of minors for venereal disease without parental consent. (However, if the minor is twelve or under, the matter must be reported as possible child abuse.) "The fact of consultation, examination and treatment . . . shall be confidential and shall not be divulged . . . including the sending of a bill for the services to any person other than the minor . . . " (Section 19a-216)

(c) *Drug abuse.* Section 19a-382 of the Connecticut General Statutes provides for treatment of a minor's drug abuse without parental consent. It prohibits the notification of parents without the consent of the minor.

(d) *Alcohol abuse.* With respect to treatment for alcohol abuse, Section 17-155t(a) of the Connecticut General Statutes provides that a minor (or his parent, legal guardian or other legal representative) can make application for voluntary treatment to a licensed public treatment facility.

(e) *Mental illness.* Sixteen and seventeen year olds are treated as adults for purposes of consent to treatment for mental illness and have the power to sign themselves into hospitals as voluntary mental patients. Once they sign themselves in, they have all of the rights of adult mental patients including the right to consent or refuse to consent to treatment and the right of control of access to their psychiatric records; a parent has no right to consent or to refuse to consent to treatment for a child sixteen or older. It should be noted that there are special statutory provisions dealing with the admission and treatment of fourteen and fifteen year olds (Sections 17-205f and 17-205h of the Connecticut General Statutes). Children under the age of fourteen may not receive treatment without parental consent.

(f) *The emancipated minor.* In addition to the special situations listed above, there is also the "emancipated minor" who can give effective consent to his own medical treatment. Connecticut law provides that if a minor of at least sixteen has entered into a valid marriage, or is on active duty with the Armed Forces, or is willingly living apart from his parents and is managing his own financial affairs, or has shown some other good cause, a court order of emancipation can be obtained. Additionally, a minor can demonstrate that he is emancipated under traditional common law standards (which are similar to the statutory standards just recited), without going through this judicial procedure.

(g) *The "mature" minor.* There is an additional doctrine which may be of assistance to physicians who face the situation of trying to decide whether to go ahead without parental consent where treatment is necessary but there is no "emergency,"* the minor is not emancipated, none of the laws cited above apply, and the parents are unavailable in spite of reasonable efforts to contact them. This is the so-called "mature minor" doctrine. The judgment which can be exercised by an individual obviously does not change between the day preceding and the day of his eighteenth birthday. The law makes a person an adult at age eighteen, but there are various situations, set forth above, in which a person under that age may give consent. It is certainly preferable to try to get parental consent in all cases where the patient is under eighteen (except in cases involving drugs and venereal disease or where a court order of emancipation has been entered or the child clearly is emancipated), but in situations where parental consent is not readily obtainable in spite of reasonable efforts to contact the parents and the patient appears mature enought, it may very well be possible if necessary to take his consent. We know of no case where a physician has been held liable for relying on the consent of a "mature" minor to treatment to be provided to the minor where the patient was fifteen or older, appeared to be mature, and was properly informed.

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*For example, delay would not increase the risks in any material way, but the child is in pain or immediate treatment is advisable for some other reason.

In the event that parental consent cannot be obtained, and it is necessary to provide treatment* upon the signature of the mature minor:

(1) care should be taken to document all of the circumstances including the medical situation and reasonable efforts to contact members of the family;

(2) the minor should be at least fifteen and appear to be capable of understanding the nature of the procedure and of giving an informed consent under the usual standards; and

(3) the minor should be as fully informed as if he were an adult and should sign the consent form.

In case of any doubt, it probably would be helpful if at least two physicians participated in the decision to go ahead with treatment, and such consultation was duly recorded in the record. As aforementioned, the second physician's report should show evidence of a review of the patient's record, pertinent findings on examination of the patient, and the consultant's opinion and recommendations.

(h) Birth control. In *Carey v. Population Services International,* the U.S. Supreme Court held that "the right of privacy in connection with decisions affecting procreation extends to minors as well as adults." More recently, a federal court of appeals held in the case of *Doe v. Irwin* that a state-supported county clinic which counseled teenagers and prescribed birth control devices, other than IUDs, without parental consent or notification was under no duty to notify parents if the teenager did not wish it to do so. (It was the policy of the clinic to encourage but not require parental involvement.) The parents had argued that their constitutional liberty interest in the care, custody and control of their minor children, long recognized by the Supreme Court, had been infringed upon by the failure to notify them. The Court of Appeals rejected their argument, and the Supreme Court refused to review the decision.

We are of the view that a physician providing counseling or contraceptives (other than IUD's or other risky devices) to a mature minor without parental consent or notification faces little risk of liability. The *Doe v. Irwin* case lends considerable support to this view.

(i) Abortion. Parental consent is not required for an emancipated or mature minor. There have been numerous legislative attempts in Connecticut to require parental consent or notification, but such proposals have been rejected. If the mature minor does not object, parental consent or notification is desirable. Where consent of the parent or guardian is not obtained, the patient's written consent should be incorporated into the medical record. A physician's determination that a minor is mature also should be noted in the patient's record. There is no need to obtain the consent of the father although in cases of known disagreement the facility may wish to provide counseling. You also should be familiar with the State Department of Health Services' abortion regulation, Section 19-13-D54 of the Public Health Code, which requires, *inter alia,* pre-operative counseling, and specifies that during the third trimester, an abortion may be performed only when necessary to preserve the life or health of the expectant mother.

Under no circumstances should an abortion be performed if the patient refuses to give her consent, irrespective of the wishes of her parents or of any other persons.

(j) Sterilization. No person under the age of eighteen may be sterilized except under extraordinary circumstances involving medical necessity.

CHILD ABUSE

Section 17-38a of the Connecticut General Statutes requires any physician who has reasonable cause to suspect or believe that a child under the age of eighteen has been abused to report orally to the police or the Department of Children and Youth Services (DCYS) immediately and to file a written report with DCYS within 72 hours.

In these cases, Connecticut law allows an examining physician the right, after reasonable attempts to advise parents or others having responsibility for the care of the child that he suspects the child has been abused, to keep a child in a hospital for up to ninety-six hours with or without consent pending study of the family and home by the welfare agency concerned. (Section 17-38a(d) of the General Statutes.) In our view, the physician may treat a child who is an apparent victim of child abuse and who has been hospitalized under a ninety-six hour "hold," without consent and may do anything incidental to repor-

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*The doctrine of the "mature" minor is available only where the benefit or procedure contemplated is for the benefit of the minor. It cannot be used for any other purpose, *e.g.*, authorization for tissue or organ donation by a minor.

ting the suspected abuse such as taking photographs, *etc.* Furthermore, since as a practical matter requiring parental authorization for release of information to the police or welfare authorities in these cases makes no sense, we conclude that the hospital and the physician need not hesitate, incidental to reporting, to make the child's medical record available to the police and the welfare authorities. Obviously, the matter should not be discussed with the media or anyone other than the police, welfare authorities, and the court.

NONTHERAPEUTIC STERILIZATION

A patient who is competent and eighteen years of age is fully capable of consenting to a nontherapeutic sterilization, and there is no need to obtain the consent of the spouse. It is of obvious importance, however, that the patient understand that the procedure is intended to render the patient permanently incapable of having children.

By "nontherapeutic sterilization" we mean an elective sterilization for purposes of birth control. This is to be distinguished from a medically-indicated or "therapeutic" sterilization such as may be necessary because of cancer, trauma, or some other serious medical condition.

It should be noted that a physician is not required to perform a nontherapeutic sterilization for a patient.

Section 45-78q of the Connecticut General Statutes provides that "[n]o person shall undergo sterilization unless such person has attained the age of eighteen years and has given informed consent, in writing, to such sterilization." Sterilization is defined as "a surgical procedure, the purpose of which is to render an individual incapable of procreating." Section 45-78z further provides that nothing in the chapter "shall limit surgical procedures which are medically indicated and which may result in sterilization" (which we refer to above as "therapeutic sterilization").

Section 45-78z also provides that "[a] hysterectomy shall not be performed for the purpose of sterilization or for the purpose of hygiene and sanitary care of a female's menses."

Section 45-78q provides that if a patient over the age of eighteen is in a state institution or appears to be incapable of giving an informed consent to a nontherapeutic sterilization, the procedure only may be performed if the probate court determines either that the person can give an informed consent or that the operation or procedure is in the best interest of the person. Application for permission of the probate court may be filed by the person seeking sterilization, the attending physician, the director of an institution, a guardian or conservator, or an interested party. A hearing must be held and the patient in question represented by counsel. It is important to note that Section 45-78w provides that even if the probate court has determined that sterilization is in the best interest of the individual, such individual, if able to understand the nature and consequences of sterilization, may still refuse the procedure and it then may not be performed.

Any consent form for sterilization should indicate that the result is not guaranteed and that the patient understands that the procedure may not be successful. It should be noted that the Connecticut Department of Income Maintenance (welfare) has issued a sterilization consent form which must be used and certain policies which must be followed before the Department will make any payment for the procedure.

ORGAN AND TISSUE DONATION

Chapter 368i of the Connecticut General Statutes, the Anatomical Donations Act, provides that any person eighteen years of age or older and of sound mind, or any person fourteen through seventeen who is of sound mind and has the consent of his parent or legal guardian, may make a gift of all or any part of his body, such gift to take effect upon death. The gift may be made by will or by a document other than a will including a card signed in the presence of two witnesses (one of the witnesses must be a parent in the case of a person fourteen through seventeen).

With respect to live donors of organs and tissue, the physician may act on the informed consent of any person eighteen years of age or older and capable of giving an informed consent. Donations by living incapables and minors should not be considered except under unusual circumstances and after consultation with legal counsel.

EXPERIMENTAL AND RESEARCH PROCEDURES

This Primer does not deal with the problem of consent to experimental or research procedures. Such procedures generally require protocols approved by so-called "Human Investigations Committees" and the use of special forms drafted in accordance with FDA and HHS requirements. Legal counsel should be consulted.

PHOTOGRAPHY AND TAPING

In the event it is intended that a procedure be photographed, videotaped, or otherwise filmed or sound recorded, it is necessary to obtain an authorization from the patient for the filming and for the proposed use of the film or recording. If the patient is identified or identifiable, it is essential that the authorization be specific and that the photograph, tape or film be used only for the purposes set forth in the authorization. It should be noted that photographs and film and sound recordings will be available through subpoena to plaintiff's counsel in the event of an action against the physician.

REFUSAL TO CONSENT

The general rule is that a competent adult patient has a right to refuse to consent to any medical or surgical procedure or treatment. If the physician proceeds in spite of such refusal, there is a risk of litigation involving claims of assault and negligence.

It is emphasized that the decision must be that of the patient, not his next of kin. Therefore, if the patient is a minor or for other reasons is not capable of consenting or refusing to consent, the physician should not merely rely on the refusal of his next of kin under circumstances where refusal would jeopardize the patient's health or well being.

In the event of an emergency, as indicated above, the physician may proceed to provide treatment if the patient is incapable of giving his consent and there is no time to obtain substituted consent. In the event that there is an emergency and a relative such as a spouse or parent refuses to give substituted consent or objects to treatment, and there is no time to obtain a court order, treatment should be provided and all of the facts recorded in the patient's record.

The question of what to do if an adult appears definitely capable of giving an informed consent but refuses emergency treatment and as a result will die or be seriously harmed is a very difficult one. If the person is clearly capable of consenting, the law provides that he has a right to refuse. Nevertheless, if standard treatment holds a high probability of saving the person's life or preserving his health, *e.g.*, an emergency transfusion, some physicians may wish to assume the risk of treating without consent. If such a patient is treated without consent and recovers without incident, it seems unlikely that a court or jury will be sympathetic to the patient's claims of assault and negligence, and clearly he will have very little to claim (if anything) in the way of damages. However, if such a patient dies or becomes very sick, there is the possibility of a successful suit against the physician who treated without consent. Obviously, when faced with such situations, physicians will have to exercise their best judgment. If the physician treats under such circumstances, he should carefully explain in the chart why he questioned the patient's ability to give an effective refusal.

Jehovah's Witnesses. Jehovah's Witnesses refuse to consent to transfusion on religious grounds. In the case of an adult Jehovah's Witness who refuses consent, the physician should obtain a written release from the patient. If the physician wishes to give the patient blood in spite of a refusal, an attempt could be made to secure an injunction in the Superior Court. Since, however, a competent adult has the right to refuse consent, chances of obtaining an injunction are practically nonexistent unless the patient has minor children. In any event, since injunction proceedings can be time consuming, the time element might be such as to preclude the possibility of effective legal proceedings.

Parents do not have the right to refuse a medically necessary blood transfusion for a minor child based on the parents' religious beliefs. If consent to transfusion of a minor cannot be obtained from either parent and time permits, a request should be made to the Juvenile Division of Superior Court for the Clerk to file a petition seeking a declaration that the child is neglected and an order directing the physician to administer the transfusion. Parental rights would be temporarily suspended and a temporary guardian appointed who could consent to the transfusion.

In an emergency where there is no time to go to court, blood may be given to the minor without consent and over parental objection. Adequate documentation of the emergency should be placed in the medical record, but there is no need to petition the court after-the-fact. The law is, as stated above, that an emergency obviates the need for consent.

THE "LIVING WILL"

On October 1, 1985, Public Act 85-606, the so-called Connecticut "Death with Dignity" or "Living Will" act, became effective. This legislation deals with what may be considered an aspect of the refusal to consent: namely, the disconnection of life support systems from an incompetent person.

In the first place, it should be pointed out that the Act does not *require* any physician or hospital to honor any patient's wishes with respect to termination of life support systems whether expressed orally or by means of what has come to be called a "living will." As set forth in section 1 of the Act, what the Act does is to protect a physician or "licensed medical facility" (which presumably includes both short and long term facilities, *i.e.*, both hospitals and nursing homes) from civil or criminal liability for the removal of life support systems in accordance with the provisions of the Act.

"Life support system" is defined as any mechanical or electrical device designed to replace, assist or supplement the function of any vital human organ. Provision of nutrition and hydration is specifically excluded from the definition of life support system.

"Terminal condition" is defined as the final stage of an incurable or irreversible medical condition which, in the opinion of the attending physician, will result in death.

Removal of a life support system from an incompetent patient is authorized by the Act only where the following four specific conditions are met: (1) the decision to remove such assistance must be "based on the best medical judgment of the attending physician," (2) the attending physician must determine that the patient is in a terminal condition, (3) the attending physician must obtain the informed consent of the next of kin if known or legal guardian if any, *and* (4) the attending physician has considered the patient's wishes as expressed by the patient directly, through his next of kin or legal guardian, or in the form of the living will as provided for in section 6. Note that the Act requires not only the expression of the wishes of the patient but also requires the informed consent of the next of kin or legal guardian.

The patient's wishes may be expressed informally or by means of the living will. Failure to execute a living will creates no presumption one way or the other concerning the wishes of the patient.

"Comfort, care and pain alleviation" must be provided in all cases. Presumably this would also include provision of nutrition and hydration since these are excluded from the definition of life support system.

The Act does not apply to competent patients; that is presumably because the competent patient is able to speak for himself and to consent to the removal of the life support system.

The Act also does not apply to a pregnant woman.

Section 6 of the Act provides that any *adult* may execute a document in substantially the form specified in the Act. While compliance with the exact terms of section 6 is not required, it is our recommendation that if an individual desires to take advantage of the Act, he should use the form prescribed by statute.* While the language of section 6 may not be completely in accordance with the wishes of all persons, it would appear to cover the basic requirements and we see no need to vary the language. Note that the form must be signed by the patient and dated and that the patient's signature requires two witnesses.

Significantly, nothing in the Act precludes hospitals from establishing standards for termination of life support systems which are different from those provided in the Act. For example, in the case of *Foody v. Manchester Memorial Hospital,* 40 Conn. Sup. 127 (1984), the Superior Court recognized the right of competent adults to refuse life-sustaining medical treatment and held as follows with regard to the removal of life support systems from an incapable semi-comatose person:

> Where the incapable patient's condition (1) is permanent and irreversible and there is no reasonable medical probability that the patient ever will return to a cognitive state, (2) the patient's attending physician together with at least two other consulting physicians unanimously concur as to the patient's condition, and (3) there are concerned family members who in good faith wish to exercise through substitute decision-making the patient's right to discontinue artificial life-support systems, it is our conclusion that the family lawfully may act as the patient's substitute decision-maker and may decide to discontinue the use of the respirator and we so hold. (40 Conn. Sup. at 140.)

THE WRITTEN CONSENT FORM

A form should record the fact that the patient was properly informed and consent was obtained. Ordinarily, it would then be up to the patient to subsequently explain why, in spite of having signed the form, his informed consent nevertheless was not obtained by the physician.

Unfortunately, both physicians and attorneys sometimes produce prolix forms which complicate rather than simplify problems of informed consent. By focusing on the written word, one can lose sight of the purpose of informed consent—giving the patient ample information so that he can make an informed decision. A study published in the *New England Journal of Medicine* in 1980 suggested that out of five representative surgical consent forms analyzed by application of two standardized readability tests, four forms were found to be written "at the level of a scientific journal, and the fifth at the level of a specialized academic magazine."* An editorial in the same issue commented that:

> . . . it seems astonishing that anyone should draw up and presumably defend unintelligible, legalistic documents that must inevitably obfuscate, intimidate, and alienate. One might easily imagine that the courts would later discount such forms as evidence of informed consent; indeed, they might find them to be evidence that the patient could not have been informed at all. (Rennie, *Informed Consent By "Well-Nigh Abject" Adults,* 302 N.E. J. Med. 917, 918 (April 17, 1980).)

The point, of course, is that a consent form should not take on a life of its own.* The focus always should be on what transpired between the physician and his patient.

EROSION OF THE STATUTE OF LIMITATIONS AND INSURANCE REQUIREMENTS

In recent years, our courts have begun to erode our statute of limitations. The statute of limitations for actions involving professional liability in Connecticut, Section 52-584 of the General Statutes, has provided for a number of years that an action must be brought within two years from the date when the injury is first sustained or discovered or in the exercise of reasonable care should have been discovered, except that no action may be brought more than three years from the date of the alleged act or omission. In other words, even if the malpractice was not obvious or could not reasonably have been discovered, an action more than three years from the date of the alleged malpractice is barred.

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*Sec. 6. Any adult person may execute a document in substantially the following form:

If the time comes when I am incapacitated to the point when I can no longer actively take part in decisions for my own life, and am unable to direct my physician as to my own medical care, I wish this statement to stand as a testament of my wishes. I . . . . (NAME) request that I be allowed to die and not be kept alive through life support systems if my condition is deemed terminal. I do not intend any direct taking of my life, but only that my dying not be unreasonably prolonged. This request is made, after careful reflection, while I am of sound mind.

______________ (Signature)
______________ (Date)
______________ (Witness)
______________ (Witness)

*Grundner, On the Readability of Surgical Consent Forms, 302 N.E. J. MED. 900 (April 17, 1980).

*Curiously, physicians too often are careless in regard to filling in the blanks in written forms. Such carelessness can prove lethal in court. *See Powers v. U.S.*, 589 F. Supp. 1084, 1098-1099 (D. Conn. 1984) (Clarie J.).

In the case of *Puro v. Henry*, decided in 1982, the Connecticut Supreme Court held that if there were evidence of fraudulent concealment of the malpractice, the three year statute of limitations would be tolled, meaning that the plaintiff could get his claim to the jury. Judge Shea in his dissent said that:

> I am concerned not only about this case, which I concede as a 'hard' one, but also about the ramifications of the majority opinion in rendering the protection afforded by the statute of limitations largely illusory in malpractice actions and perhaps in others. In virtually every case the wrongful conduct is susceptible of two possible explanations: (1) that it was inadvertend and (2) that it was intentional at least in the sense that the defendant was aware of his error and failed to reveal it. The majority would give the jury complete freedom to choose the second alternative without any indication from the evidence that the case presented a rare occasion of villainy rather than a common instance of negligence. This deference to the trier leaves virtually any professional exposed permanently to a claim that he had actual knowledge of his misconduct when it occurred and that, by failing to disclose it, he is guilty of fraudulent concealment which removes the statutory bar.

Two years ago, in the case of *McDonald v. Haynes Medical Lab*, a Superior Court judge held the three year statute of limitations unconstitutional. He said that the statute does not give the plaintiff enough time to discover the injury. In his opinion, the judge cited an Arizona case, *Kenyon v. Hammer*, which had reached the same result.

However, a more recent case in the federal Court of Appeals for the Tenth Circuit, *Brubaker v. Cavanaugh*, reached the opposite conclusion and held that a similar statute of limitations in Kansas was constitutionally acceptable.

If the three year statute of limitations is nullified, then physicians not only will face potential liability going back for many years, but if they have insurance policies which are written on a claims-made basis (in other words, policies which cover them only for claims made during the term of the policy), it is essential that they purchase so-called "tail" insurance when they retire or cease practice since they will be exposed to potential malpractice claims for a number of years.

Editor's Note: *At present Connecticut insurance law requires carriers writing claims-made malpractice insurance to offer complete "tail" coverage. Such policies now being offered provide permanent coverage of prior acts. Medical society-endorsed programs here have offered a "modified" claims made policy which provides paid-up tail coverage upon an insured's death, disability, or normal retirement after at least five years in the program; in other circumstances, this "reporting endorsement" must be purchased. Only authorized company agents can give the complete details of these programs as they may apply to particular circumstances.*

NOTICE TO CONTRIBUTORS

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Drug Concentrations and Driving Impairment

NATIONAL INSTITUTE ON DRUG ABUSE

Most drugs that affect the central nervous system have the potential to impair driving ability. For many years, alcohol (ethanol) has been the drug of greatest concern, since it is, by far, the most frequently recognized cause of drug-impaired driving. Yet as more therapeutic agents, such as benzodiazepines, are introduced and widely used, and as social use of unsanctioned drugs such as cannabis (marijuana) increases, attention must be directed toward other drugs.

The National Institute on Drug Abuse sponsored a conference on drugs and driving in Durham, NC, in October 1983. The objective was to reach a consensus on several key issues associated with the current state of knowledge about the relationship between body fluid concentrations of drugs and their pharmacologically active metabolites and degree of driving impairment. It was also of interest to ascertain whether a sufficient body of knowledge exists for an expert to form an opinion, which will meet the applicable standards of proof for legal proceedings, that a person's driving ability was impaired based on body fluid concentrations of a drug. The consensus panel, representing the disciplines of clinical pharmacology, analytical and forensic toxicology, law, and forensic medicine agreed on answers to the following questions:

1. Is ethanol a good model for other drugs?
2. What drugs might have a potential for impairing a driver?
3. How is driving impairment measured?
4. What is known about correlations between driving impairment and drug concentrations?
5. Could "per se" concentrations be established for drugs other than alcohol?
6. Can impairment be established from body fluid concentrations?

Panel's Conclusions

As the use and abuse of psychoactive drugs escalate in the US population and improvements in chemical analysis techniques continue to lower the detectable concentrations, expert witnesses are more and more frequently faced with the need to provide expert opinions concerning the possible impairment of driving ability based on body fluid concentrations of such drugs. This requires access to a body of knowledge on the measurement of driving ability, the chemical analyses of body fluids, and particularly the correlation and interpretation of those measurements. Such a body of knowledge is not yet sufficient for dealing with drugs such as marijuana, sedative-hypnotics, antihistamines, and benzodiazepines. Sensitivity to the complex issues relating to these measurements and their interpretation is of prime importance to both the forensic expert and the legislative bodies concerned with the effect of drug use on traffic safety. Further research should be given high priority and designed to dovetail with legislative initiatives.

In order to establish that use of a drug results in impairment of driving skills and to justify a testing program to respond to this hazard, certain facts must be available. (1) The drug can be demonstrated in laboratory studies to produce a dose-related impairment of skills associated either with driving or with related psychomotor functions. (2) Concentrations of the drug and/or its metabolites in body fluids can be accurately and quantitatively measured and related to the degree of impairment produced. (3) Such impairment is confirmed by actual highway experience. (4) Simple behavioral tests, such as can be done at the roadside by police officers with modest training, can indicate the presence of such impairment to the satisfaction of courts. (5) A range of concentrations of the drug can be incorporated in laws relating to impaired driving as ipso facto evidence.

These criteria have been met for ethanol. It is not certain that they can be met for other drugs that are now of concern to highway safety.

From the Research Technology Branch, National Institute on Drug Abuse, Rockville, Md.

Reprint requests to Research Technology Branch, Room 10A-13, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, MD 20857 (Richard L. Hawks, PhD).

The development of methods for testing the effects of ethanol on driving skills and relating these to body fluid concentrations took many years. It is obvious that a beginning has just been made to develop similar information about other drugs of similar interest. Before establishing meaningful legislation based on cause-and-effect relationships of drugs and driving, further studies are required. Goals for future research efforts should include the following:

- **Experimental subjects should be tested under conditions that resemble real-life driving experiences after they have been exposed to various acute and chronic dosage regimens of a drug, or combination of drugs.**
- **A set of behavioral tests needs to be established, such as might be performed at the roadside, that may augment present roadside sobriety tests and that may indicate the influence of other drugs.**
- **Drugs for which a range of concentrations in body fluids may be defined in which driving would be impaired should be identified.**
- **Valid micromethods for measuring body fluid concentrations of drugs need to be developed. This will not only enable easier acquisition of smaller sample size but will permit replicate tests, an important consideration in minimizing analytical error and the occurrence of outliers.**
- **First priority for such research should be studies with marijuana and benzodiazepines, as these two types of drugs are those most commonly used.**
- **Additional studies are necessary to examine effects on driving behavior when drugs are used in combination with ethanol or other drugs.**

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1. Is Ethanol a Good Model for Other Drugs?

Traditionally, ethanol has been the drug of greatest concern in relation to driving impairment. Ethanol is by far the most frequently documented drug in fatal motor vehicle accidents. Measurements of ethanol in blood have been available for more than a century, and blood concentrations of ethanol have long been studied in the context of driving impairment so that relationships have been established. The concentration of ethanol in breath can be measured noninvasively. In addition to its relatively low toxicity, ethanol has many pharmacokinetic differences from other sedatives: it is both water and lipid soluble, it is distributed in the body water and is not bound to plasma proteins, it produces no long-lived active metabolites, and it equilibrates readily between blood and brain. Thus, ethanol has provided an unusually good model for studying the effects of a drug on driving performance. Other drugs of concern do not share these characteristics and therefore generalizations cannot be made from the ethanol model to other drugs that might impair driving skills.

Our knowledge concerning ethanol is far from complete, and there are areas of concern that warrant further elucidation.

2. What Drugs Might Have a Potential for Impairing a Driver?

New drugs of concern are primarily those with predominant effects on the central nervous system that cause significant alterations in cognition, mood, or psychomotor functions. Among licit drugs, our major concern is with drugs such as benzodiazepines, sedative-hypnotics, other psychotherapeutic agents, stimulants, and some antihistamines. Among illicit drugs, a major concern is with cannabis, cocaine, opiates, and hallucinogens such as lysergic acid, diethylamide, and phencyclidine. Although technically it is now possible to measure all these drugs quantitatively in body fluids, practical considerations limit the number to be tested in an initial screen. There are very few laboratories prepared to identify and quantitate the low concentrations of drugs that are expected to be found in impaired drivers. Epidemiologic evidence from fatally injured driver studies suggests that the most likely drugs to be associated with impaired driving are ethanol, sedative-hypnotics, cannabis, and antihistamines. Also the fact that benzodiazepines are among the most highly prescribed therapeutic drugs make them candidates of interest. Thus, initial screening analyses should test for these drugs.

Ambiguous Effects of Therapeutic Drugs

Although psychoactive drugs are those most commonly thought to cause impaired driving, their mere presence in body fluids cannot be construed as evidence of impairment. It can be speculated that a chronically anxious, preoccupied, and irritable person might be more impaired by the prevailing mental state than that caused by an antianxiety drug if it were used to alleviate these symptoms. In a similar vein, persons with schizophrenia or depression could be more impaired if untreated than if they were appropriately taking antipsychotic or antidepressant medication. Persons with epilepsy are generally not allowed to drive unless they are taking anticonvulsants, even though some of these, such as phenobarbital or carbamazepine, are potentially impairing. In such cases, the adverse effects of the drugs in therapeutically effective concentrations are deemed to pose much less risk than that posed by the disorder they treat. Although not considered here it must also be recognized that some drugs that are not primarily psychotropic may cause sedation and possibly effect driving skills.

3. How Is Driving Impairment Measured?

Operational definitions of impaired driving have been based largely on experience with ethanol. We are not sure that the same types of impairment would be produced by other drugs except perhaps by sedative-hypnotics. We also have no universal definition of acceptable driving behavior. Licensing is usually based on written tests of knowledge of rules of the road and performance in a short driving test. Whether these simple procedures are adequate to ensure that all licensed drivers are capable of safe operation of a motor vehicle is uncertain. Further research is needed to fix the boundaries of acceptable driving skills as well as to determine whether drugs other than ethanol produce characteristic patterns of impaired driving.

Determination of Impaired Driving

Impairment of driving performance is, in the most general sense, a failure to exercise the expected degree of prudence or control to ensure safe operation of the vehicle. Manifestations of such impairment are many: driving at a speed that is inappropriate to the flow of surrounding traffic, weaving within a lane of traffic or frequent lane changes, following cars too closely, failing to signal major changes of course, failing to observe traffic signs or signals, as well as many others. These are the signs of impairment that, when observed by law enforcement officers, merit investigation. These signs are not specific to effects produced by drugs. They may be associated with distractions of the driver, fatigue, physical illness, symptomatic emotional disorders, and many other non-drug-related causes. Law officers usually employ roadside sobriety tests, which, on the basis of extensive experience, are adequate to support the opinion that some impairment of psychomotor function was the cause of the observed erratic driving behavior. The determination of the concentration of ethanol or other psychoactive drugs in body fluids may be critical to a decision about the true cause of impairment.

Laboratory Studies of Driving Skills

Most studies of the effects of drugs on driving employ various tests of combined cognitive and motor functions presumed to be pertinent to those skills associated with motor vehicle operation. If the tests are made difficult enough, or the doses of drugs being tested are high enough, it is generally possible to show impairment for any psychoactive drug. Most such tests are novel to the person being tested. Even though subjects may have been given enough practice to learn the test to some acceptable criterion, it is not the same situation as with a potentially overlearned behavior such as driving. Thus, it is difficult to translate the results of such testing to actual driving ability.

Tests using driving simulators are probably more appropriate. Many simulators are now available that mimic to a remarkably good degree the actual conditions of driving. A few studies have used the actual driving situation, either on devised courses or in actual traffic, but devised courses are not easily found and driving in actual traffic under the experimental influence of a drug is not socially acceptable. When tests are done under controlled conditions, subjects are usually studied when they are well rested. They are hardly comparable with drivers who may have been awake for 16 hours and who are preoccupied with the events of the preceding day. Thus, extrapolations from experimental studies are of limited value in applicability and validity.

4. What Is Known About Correlations Between Driving Impairment and Drug Concentrations?

Except for ethanol, determinations of drug concentrations in body fluids are at present of limited value for establishing driving impairment. Adequate information on correlations of body fluid concentration of drugs with measurements of behavioral impairment are rare. Data currently available indicate that wide ranges of drug concentrations may be present at equal levels of impairment; also, evidence of impairment is often lacking in some subjects at drug concentrations that are associated with impairment in others. Many factors contribute to these variations: differences in body weight and composition in relation to dose; genetic and environmental influences that affect rates of drug metabolism and elimination; the phenomenon of hysteresis, in which drug effects are greater as blood concentrations are rising than at the same concentrations when they are failing; the degree of prior exposure to the drug in question or other drugs that can lead to tolerance or cross-tolerance to the effects of the drug; and the presence of other drugs that may lead to pharmacodynamic or pharmacokinetic interactions. The major value of such determinations is to suggest that demonstrated clinical impairment of function is probably related to the presence of the drug in the body fluid, in the absence of other reasonable explanations. Conversely, impairment of function without the presence, in significant amounts, of a drug that might be expected to produce impairment would strongly suggest some cause, unrelated to drug use.

5. Could "Per Se" Concentrations Be Established for Other Drugs?

A simple solution to the problem of interpreting the relationship of body fluid concentrations to driving impairment would be to take an arbitrary approach. Such approaches have been taken in regard to ethanol, where certain blood concentrations, which differ from one jurisdiction to another, have been legislatively defined as per se evidence of impairment. One difficulty is that the blood concentration-impairment relation is more complex with other drugs than it is with the relatively simple drug ethanol. Conservatively, a per se drug concentration might be selected that could be expected to produce impairment in virtually all cases. The problem with this approach would be that many drivers impaired at lower concentrations would not be caught in this net. On the other hand, if a minimum concentration is chosen, below which impaired driving is unlikely in virtually all cases, the system might net too many unimpaired drivers. If both minimal and maximal concentrations could be defined, the intermediate gray area would still have to be resolved by clinical evidence of impairment. Thus, relatively little would be gained by a per se approach based on arbitrary data. In many cases, it may only be possible to use concentrations to establish legal presumptions. A further difficulty with a per se approach is the unrealistic burden it places on a laboratory measurement. It has a potential of deciding guilt or innocence solely on the basis of a single laboratory measurement. Such a potential should be avoided since unexplained outliers, administrative errors, or other factors can lead to a miscarriage of justice.

6. Can Impairment Be Established From Body Fluid Concentration?

A great need exists for more research relating body fluid concentrations of drugs to impairments of mood, cognition, or psychomotor functions in the context of driving ability. Studies done thus far relate mainly to functions that can only be presumed to be pertinent to driving performance. Use of driving simulators may be more appropriate, but actual driving of vehicles over some test course is probably the best model. Relatively few such facilities are available. Another problem is that virtually all studies use only single doses of a single drug. The effects on single doses of drugs are often quite different from those that follow a chronic dosage regimen. Yet drugs involved in motor vehicle accidents have often been taken chronically and frequently in combinations of two or more drugs. Obstacles to doing research in subjects exposed to chronic regimens of multiple drugs are formidable but not impossible to overcome. Timing of body fluid sampling for determination of time course/concentrations should be planned with careful consideration of the pharmacokinetics of the drug and its psychoactive metabolites. Specimens should generally be taken as close as possible to the actual performance of tests. Even the most meticulous experimental procedures may not be entirely pertinent to the real-life situation, but it is to be expected that they would assist greatly in the interpretation of body fluid concentrations in relation to impaired driving.

Difficulties in Interpretation

At present we cannot define critical body fluid concentrations above which all would be impaired and below which all would lack impairment. For reasons already discussed and many others, the presumed gaussian distribution curve relating impaired driving ability at a given drug concentration against numbers of individuals is probably broad, flat, and diffuse for most drugs. Furthermore, there are problems of interpreting drug concentration in patients undergoing chronic drug therapy. Again, attempting to mimic the ethanol model poses a dilemma. Nonetheless, measurement of blood concentrations of drug has value in establishing a possible cause of impaired driving. In this regard, such determinations would be analogous to the function of other clinical laboratory tests; that is, they do not establish the diagnosis by themselves, but taken in conjunction with clinical observations and circumstantial evidence, they can help either to support or exclude a diagnosis of impairment due to a specific drug.

Difficulties in Obtaining Blood Specimens

Practical considerations make determining blood concentrations of drugs more difficult under field conditions than determining ethanol concentrations, which can be measured with a great degree of accuracy with a noninvasive breath test that is administered quickly and easily. To obtain blood specimens in the field requires consideration of logistical and technical complexities. Withdrawal of blood requires qualified, licensed personnel. These personnel are available in hospitals and clinical laboratories, but many hospitals do not allow such procedures unless the subject has been admitted to the emergency room. Medical technologists can be available to law enforcement agencies on an "on call" basis. The expense for this would be less than that for admission to an emergency room, but to be effective, qualified personnel must be available to the arresting officer on a continuous basis. Any delay will generally result in finding different drug concentrations than those that existed at the time of the offense. The problem of delay in acquiring a blood specimen and estimating an earlier blood concentration is not unique to measuring drugs. The same problem exists with blood ethanol measurement. Moreover, most drugs follow a blood concentration-time course profile obeying first-order kinetics and are subject to a host of confounding variables.

Determination in Urine

Testing of drugs or drug metabolites in urine is only of qualitative value in indicating some prior exposure to specified drugs. Inferences regarding the presence or systemic concentration of the drug at the time of driving or impairment from drug use are generally unwarranted. The presence of an illicit substance in urine that may indicate prior illegal action can, however, add a dimension to probable cause of observed driving performance.

Members of the Consensus Development Panel were Robert V. Blanke, PhD, Richmond, Va; Yale H. Caplan, PhD, Baltimore; R. Thomas Chamberlain, PhD, JD, Memphis; Kurt M. Dubowski, PhD, Oklahoma City; Bryan S. Finkle, PhD, San Francisco; Robert B. Forney, PhD, Indianapolis; Richard L. Hawks, PhD, Rockville, Md; Leo E. Hollister, MD, Palo Alto, Calif; Peter I. Jatlow, MD, New Haven, Conn; Roger P. Maickel, PhD, West Lafayette, Ind; Arthur J. McBay, PhD, Chapel Hill, NC. Other participants included Michael Walsh, PhD, National Institute on Drug Abuse; Ted Anderson, Department of Transportation.

The conference was sponsored by the National Institute on Drug Abuse, Research Technology Branch, Richard L. Hawks, chief.

Flecainide

EDMUND CAPPARELLI, PHARM.D.

Introduction

Flecainide (Tambocor®), is the first of a new class of antiarrhythmic agents available in the U.S. Its current FDA approved indication is the treatment of ventricular arrhythmias, but flecainide may also prove to be an effective agent in the treatment of various supraventricular arrhythmias.

Pharmacology and Pharmacokinetics

Flecainide is classified by the Vaughan Williams criteria as a Type I-C antiarrhythmic agent and has electrophysiologic properties similar to the investigational agents lorcainide and encainide.[1] In isolated canine Purkinje fibres, flecainide has been shown to greatly decrease phase 4 depolarization and Vmax without significantly affecting the effective refractory period. It's effect on action potential duration is varied ranging from no effect to a mild increase or decrease depending on species, tissue, and concentration.[1-4] Clinical studies in patients with ventricular arrhythmias have shown flecainide to increase sinus node recovery time, increase the AH and HV interval, and mildly increase atrial (not statistically significant) and ventricular (statistically significant) effective refractory periods.[5] On the electrocardiogram flecainide produces widening of the QRS, an increase in the PR interval and an increase in the QTc due to the widened QRS.

Flecainide produces minimal changes in blood pressure and heart rate but does possess negative inotropic effects.[6,7] A decrease in cardiac output, ejection fraction and increase in pulmonary capillary wedge pressure (PCWP) has been noted after intravenous administration of flecainide.[8] During chronic oral therapy, in patients with pre-existing heart failure, flecainide has been well tolerated in general, but on rare occasions does exacerbate heart failure enough to require cessation of therapy.[7] Heart rate may be decreased minimally but caution should be used in patients with sinus node disease as there are reports of flecainide precipitating severe bradycardia and sinus arrest. Flecainide's potent effect on conduction in the His-Purkinje system can precipitate various forms of bundle branch block. It is prudent to have a prophylactic pacing wire inserted in patients with bifasicular disease before flecainide therapy commences due to the possible development of complete heart block. In addition flecainide can increase endocardial pacing thresholds, therefore, patients with pacemakers should have pacing threshold checked after institution of flecainide.

Flecainide is well absorbed after oral administration (at least 90%) and does not appear to undergo first pass metabolism.[9] Peak levels usually occur 2 to 4 hours (range 1 to 7 hours) after an oral dose and are not significantly altered by food or antacids.[10] The volume of distribution varies greatly between patients from 5 to 13 liters/kg, mean 9 liters/kg, and the drug is about 40% bound to protein in serum. This binding is independent of plasma drug concentration and is not affected by the presence of other antiarrhythmic agents, but may increase transiently after a MI.[10] In subjects with good renal function, approximately 30% of an oral dose is excreted unchanged in the urine while the majority undergoes O-dealkylation to form a weakly active metabolite which is relatively quickly conjugated to an inactive compound and eliminated in the urine. Flecainide elimination is not significantly influenced by normal urinary pH changes (pH 5-7) but under marked alkaline or acidic conditions elimination may be reduced or enhanced respectively. The terminal half-life (t ½) of flecainide averages between 11-16 hours in healthy subjects and 19-22 hours in patients with VPBs.[9] The elimination of flecainide in patients with end stage renal disease is reduced and accordingly the t ½ is increased up to an average of 26 hours.[12] In a study of patients with CHF (NYHA functional class III), their t ½ was longer than that of healthy subjects (19 versus 14 hours) but not significantly different than that in patients in other studies with ventricular ectopy.[13] No studies have been undertaken to determine the effect of hepatic disease on flecainide kinetics but dose

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reduction may be necessary to prevent toxic concentrations due to reduced metabolism.

Plasma concentrations between 255 and 980ng/ml have been shown to correlate with 90% VPB suppression.[14] Increased side effects have also been seen in higher concentrations such that levels of 1000ng/ml were associated with a frequent occurrence of blurred vision and dizziness.[14] The manufacturer recommends that troughs be maintained below 700-1000ng/ml.

Clinical Studies

Flecainide has been evaluated in the treatment of chronic VPBs, ventricular tachycardia (VT), and in a variety of supraventricular arrhythmias.

Flecainide has a very potent VPB suppressive effect and in a multicentered trial was found to be superior to quinidine in this respect. In 280 patients with greater than 30 VPBs/hr, flecainide reduced VPB frequency by greater than 95% in 75% of the patients and by 80% in 85% of the patients. In the same study quinidine achieved 95% suppression in only 34% of the patients and 80% reduction in 57% of patients while incurring the same frequency of side effects as flecainide. Patients who had runs of VT also achieved better suppression with flecainide than with quinidine.[7] The results of studies examining flecainide's ability to suppress VT are also encouraging. Flecainide was found to prevent programmed electrical stimulation (PES) induced VT in 65% in one group of 40 patients[15] and in 60% of another 15 patients with refractory PES induced VT.[16] Holter monitoring was used to evaluate flecainide efficacy in a group of 36 patients with drug resistant VT and 27 (75%) had complete elimination of VT by initial holter. Subsequently 6 (16%) developed incessant VT and expired. These were all patients with low ejection fractions (mean 0.24), receiving large doses of flecainide, and had recently received a class Ia antiarrhythmic prior to flecainide which may have contributed to the proarrhythmic effect.[17]

In more limited studies involving supraventricular arrhythmias, flecainide successfully terminated intranodal AV reentrant tachycardia in 12 out of 14 patients.[18] Twelve patients studied with Wolff-Parkinson-White (WPW) syndrome treated with flecainide demonstrated depression of both anterograde and retrograde conduction of the accessory pathway leading to elimination of circus movement tachycardia in all but one patient. In addition, flecainide also greatly slowed ventricular response in the patients with WPW and atrial fibrillation.[19] Patients with new onset atrial fibrillation, 18 out of 24 (75%) had conversion to sinus rhythm after an intravenous loading dose of flecainide.[20]

Adverse Effects

The most common adverse effects seen with flecainide are dizziness and blurred vision both of which occur in about 30% of patients. These side effects which are commonly seen together are dose related and often disappear with dose reduction. Other common extra-cardiac adverse effects include headache (10%), nausea (10%), and asthenia (5%). In long term studies these adverse experiences result in discontinuation of therapy in 10% of patients.[21]

The incidence of proarrhythmic effects of flecainide has been noted to be between 5-12%.[22,23] While the proarrhythmic rate is not significantly higher than what has previously been reported with conventional agents, the occurrence of intractable ventricular tachycardia resistant to electrical cardioversion induced by flecainide is a new and serious complication not seen with conventional agents. These more serious proarrhythmic effects tend to occur most frequently in patients with poor left ventricular function, at plasma concentrations greater than 1000ng/ml and possibly when combined with class Ia antiarrhythmic agents.

Dosing

Flecainide is supplied as scored 100mg tablets and the initial adult dose of flecainide for the treatment of ventricular arrhythmias is 100mg bid. Dose increases are recommended no more frequently than every 3 to 4 days. Careful plasma concentration monitoring is highly recommended in patients with significant pre-existing left ventricular dysfunction since they are more prone to negative iontropic and proarrhythmic effects. Frequent monitoring is also suggested in patients with renal or hepatic dysfunction and in those which a total daily dose of greater than 400mg is used due to an increased risk for accumulation to toxic concentrations. Lidocaine is the suggested agent to use in the interim after beginning flecainide therapy and before flecainide plasma concentrations achieve steady state.

Average Wholesale Price—$50.00/100 tablets.

Conclusion

It is currently unknown how large a role flecainide will have in the management of patients with ventricular arrhythmias. While it has been shown to have superior VPB suppressing properties compared to conventional agents, experience with it in ventricular tachycardia, although encouraging, is still rather limited. Convenient twice daily dosing and flecainide's relatively low side effect profile results in good patient acceptance. Its disturbing propensity to worsen arrhythmias in a select group of patients warrants caution when used in patients on other antiarrhythmics, with poor left ventricular function, possessing significant conduction disease or receiving large doses. Therefore, until more experience with flecainide is obtained, it should remain a second line agent for patients with ventricular arrhythmias refractory to or intolerant of conventional agents.

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Report of Panel on Lasers in Medicine and Surgery

AMA COUNCIL ON SCIENTIFIC AFFAIRS

(First of Two Parts)

PART I

Lasers are in routine clinical use in many medical and surgical specialties, and a variety of new uses are under investigation. The Panel on Lasers in Medicine and Surgery has prepared a two-part report: Part I is a review of the biophysics, safety-in-use and federal regulation of lasers used in medicine and surgery; clinical applications of lasers are summarized in Part II.

Laser Action and Laser-Tissue Interactions

The LASER (acronym for Light Amplification by Stimulated Emission of Radiation) is based upon relatively simple physical phenomena. Atoms, molecules or ions contained in a laser's optical cavity can be excited by the absorption of thermal, electrical or optical energy that is directed into the cavity from an energy source.

After absorption of energy, the atoms spontaneously emit an equivalent quantity of energy in the form of light. This "spontaneous emission" will radiate in all directions and much will eventually dissipate in the form of heat.

A small percentage of the spontaneously radiated photons ("packets" of light) will travel along the axis of the laser cavity. When these photons collide with atoms that have previously absorbed energy and are in an upper energy state, the collision produces two photons traveling in the same direction and of the same wavelength. This process is referred to as stimulated emission of radiation. The photons resulting from stimulated emission will collide with additional excited atoms and more intracavity energy will develop.

The intensity of the intracavity energy is amplified by multiple reflections between parallel mirrors at each end of the cavity, causing even more collisions. A portion of the energy is permitted to escape out of the cavity through a partially transparent front mirror. This energy, the laser beam, is in the form of intense monochromatic light that can be concentrated to produce surgical effects.

The effects that optical radiation may have on tissue can be separated into categories depending on (1) the portion of the spectrum (wavelength) that is incident on the tissue and (2) the intensity (power density or irradiance) of the radiation. Wavelength is expressed in nanometers (nm) or billionths of a meter; irradiance is energy delivered divided by area exposed.

The ultraviolet portion of the spectrum, (100-400 nm) has principally a photochemical effect rather than a thermal reaction effect on tissue. At high irradiance these wavelengths break intramolecular bonds and are capable of creating tissue incisions.

The visible region of the spectrum (from about 380 nm to 700 nm) has many effects on the body, frequently mediated by absorption of radiation by various pigments in tissue. Important absorbing pigments in the pigment epithelium and choroid of the eye are xanthophyll, melanin and hemoglobin. If the intensity of the radiation is great,

PANEL ON LASERS IN MEDICINE AND SURGERY

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This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. This report reflects the views of scientific literature as of December 1985.

the absorbed energy is converted into excess heat and can cause thermal damage. The thermal effect of light on tissue depends on the wavelength (color) of the incident beam and the absorption characteristics of the tissue and chromogen.

Electromagnetic energy in the near infrared portion of the spectrum (780 nm to 3000 nm) can cause skin and retinal burns as well as cataract formation with excessive exposure. At longer wavelengths, the mid to far infrared portion of the spectrum (3000-10,000 nm), tissue effects are limited to the superficial layers. At 10,600 nm, the wavelength of emission of the CO_2 laser, radiation is heavily absorbed by the water in cells.

Energy deposited in a tissue is the product of the power of the laser and length of time that the beam is in contact with the tissue. The duration of exposure of the energy is an important variable in controlling both desired and unwanted effects on tissue. The desired effect may be vaporization of tissue (transformation of solid and liquid component of the tissue to vapor) or a controlled thermal coagulation. In contrast, the undesirable effect may be excessive coagulation necrosis and edema.

Other factors determining the effect of optical radiation include circulating blood supply which acts to cool the tissue, and the specific heat and thermal conductivity of various tissues.

Safety in Use

Hazards created by laser use are primarily acute. Direct laser radiation may damage the retina, cornea and skin, depending upon laser type. Use of lasers may be associated with electric shock, fire, explosion of volatile gases in the operating room, and ultraviolet radiation from discharge tubes. Noxious fumes from vaporized tissue may be an environmental hazard.

Chronic hazards have largely not been observed. They may become more urgent in the future with wider use of lasers operating at very short wavelengths.

Groups at risk include patients, laser operators and ancillary personnel, and persons who may be inadvertently exposed to hazard in a health-care setting.

Protection of the patient in a clinical setting mandates that the laser medical or surgical procedure have a proven efficacy with a reasonable risk-to-benefit ratio. The physician performing the procedure must have the necessary clinical skills as well as knowledge of laser hazards and safety. The patient should be protected from inadvertent laser radiation or other laser-associated hazard to the maximum extent practical under circumstances of the procedure being performed.

Patient protection necessitates clear indications for laser use, appropriate clinical and safety-related training for physician operators and those assisting in laser use, and development of standard operating practices for each procedure.

Safety for the physician and support personnel also requires training, use of standard operating practices, and physicial protection.

Protection of persons who may be inadvertently exposed

Table 1

Laser Type	*Wavelength (nm)*	*Absorber*	*Typical Power (w)*	*Operating Mode*	*Principle Application/Remark*
Carbon Dioxide	10600	Water	10-100	CW, Gated Super Pulsed	Surgery – Cutting of tissue by vaporization with very little coagulation necrosis
Nd:YAG	1060	Non-Specific	< 100	CW	Photocoagulation – Deep Thermal Necrosis G.I. Bleeding, Bronchial Ca
			< 100 MJ High Pwr	Q Switched	Photoablation – Little thermal damage, mechanical effect. Ophthalmology – membrane ablation
Ruby	694	Melanin Cytochromes	> 5J High Pwr	Pulsed Only	Photoablation – high energy pulses selectively vaporize. Dermatology – Plastic Surgery
Argon	488,514	Hemoglobin Melanin	1-10	CW Typ	Photocoagulation – Superficial coagulation. Ophthalmology – Retinal and Anterior Segment Dermatology and Plastic Surgery – Port Wine Stain
Dye	400-900	Wavelength Dependent	0.1-2	CW Typ	Photodynamic Therapy Certain low power Dermatology and Plastic Surgery applications
Excimer	193,248	Melanin Protein		Pulsed	Currently Research only. Dermatology, Plastic Surgery & Ophthalmology – cuts with no visible necrosis. No hemostasis.

to laser hazard is a problem both inside and outside the operating room. More lasers are being installed for use outside operating theaters, where patients in a waiting area or even the general public may be exposed to direct or reflected radiation. Guarding the operating room against inadvertent entry has been a vigorously debated topic, the issue being whether the use of non-defeatable door locks could result in a laser being turned off at a critical time and jeopardizing the patient. The American National Standards Institute's (ANSI) Z-136 Committee has resolved the issue by allowing alternative control measures in proposed changes to ANSI Standard Z 136.1.

Table 2
LASER-TISSUE INTERACTIONS

Thermal Effects

Photocoagulation: Target tissues are heated to temperatures high enough to induce chemical changes that produce local inflammation and scarring.

Photovaporization: Target tissues are heated to temperatures high enough to vaporize intra- and extracellular fluids, producing an incision in target tissues while adjacent vessels are cauterized to provide a largely bloodless operating field. Photovaporization also is used selectively to remove lesions from skin or membrane surfaces.

Ionizing Effects

Photodisruption: Molecules in target tissue undergo rapid ionization from a high-irradiance laser beam, creating an acoustic shock wave that disrupts tissues.

Photochemical Effects

Photoablation: Target tissue is volatilized by short-pulsed ultraviolet radiation.

Photodynamic Therapy or Photoradiation: Intravenously-administered hematoporphyrin derivative (HPD), a photosensitizer, concentrates selectively in metabolically active tumor tissue. Later exposure of the tumor tissue to red laser light of a specific wavelength produces cytotoxic free radicals that selectively destroy the HPD-containing tissue.

Principal safety concerns and considerations for protection:

Anesthesia management is essential to prevent ignition of violatile gases, one laser hazard with potential to kill a patient. Patients undergoing endoscopic or open laser procedures on internal organs are often under general anesthesia. In the case of laser surgery of the upper aerodigestive tract, the laser beam and the endotracheal tube carrying volatile gas may be in very close proximity. Safety requires detailed attention to:

- selection of a nonflammable anesthetic
- mixtures of O_2 with nonflammable gases, when indicated by risk level of a procedure, to adequately oxygenate the patient at the lowest potential for fire
- use of an endotracheal tube that offers maximum resistance to penetration by the laser beam (wrapping the tube with reflective metallic tape has been used successfully); laser penetration of a tube carrying oxygen could result in an intraluminal, blow-torch fire
- penetration protection for the cuff of the endotracheal tube (inflation of the cuff with saline, use of wet cottonoids and use of the operating platform).

Eye protection for patients, physicians and ancillary personnel is adapted to the specific wavelength of the laser being used. The transparent glass or quartz glasses that protect against the CO_2 laser beam are useless as protection against visible light. Most glasses have side protectors to prevent injury from reflected beams. Selective filters are available on endoscopes to protect the physician-operator against internally deflected beams.

Skin protection of the patient against CO_2 laser beam is accomplished by covering all exposed skin and mucous membranes outside of the surgical field with a double layer of saline-saturated towels, sponges or pads. Teeth in the operative field must be protected with a wrapping of material appropriate to the laser wavelength.

Smoke evacuation from the operating room is desirable and probably essential where an infrared laser is being used to vaporize tissue. A recent report indicates that the smoke created by CO_2 beam-tissue interaction may be mutagenic. Smoke and carbonaceous debris must be continuously evacuated by suction from the endoscopic operative field.

Instruments used in laser surgery should have low specular or direct reflectance, and large diffuse or scattered reflectance of a misdirected laser beam. Selection of rigid versus flexible endoscopes for laser surgery must be made on the basis of appropriateness to the procedure; availability of flexible endoscopes should not deter the surgeon from using rigid instrumentation that gives better control of the field.

A hospital or other facility using lasers in medicine or surgery should have a formal program in safety. Minimum requirements include: a Laser Safety Committee to approve indications for specific laser procedures, to approve standard operating practices, and to credential physicians and ancillary staff who will be involved with use of lasers; a Laser Safety Officer to select appropriate protective equipment, inspect and evaluate laser systems, review standard operating practices, and monitor laser use in the facility.

Major elements of a hazard-control program are:

- Determination of the specific hazards associated with each laser in use
- Training of physicians, other operators and ancillary personnel in safety procedures associated with each laser
- Installation of each laser with the engineering and administrative controls appropriate to its level of hazard
- Obtaining from the manufacturer all information on levels and types of hazard for each laser, and descriptions of changes in hazard level associated with different focusing systems and with auxiliary elements.

Federal Regulation

Laser medical devices are regulated by the Food and Drug Administration (FDA) under two laws, the Medical Device Amendments of 1976 to the Food, Drug and

Cosmetic Act, and the Radiation Control for Health and Safety Act of 1968, an amendment to the Public Health Service Act. The regulations under these acts impact primarily upon the manufacturers of devices that are intended to be introduced into interstate commerce.

The fundamental principle of the Medical Device Amendments is that devices entering the marketplace must be reasonably safe and effective for their intended use. Clinical aspects of the law include:

- Classification of devices into one of three classes based on the needed level of regulation
- General controls
- Performance standards
- Premarket approval
- Exemptions for investigational devices
- Notifications and regulatory remedies.

Devices are classified according to the degree of control believed to be necessary to assure reasonable safety and effectiveness:

- Class I—Devices for which general controls are considered adequate to assure safety and effectiveness.
- Class II—Devices for which, in addition to general controls, compliance with a performance standard is considered necessary.
- Class III—Devices for which the FDA believes that specific premarket approval is also necessary to assure safety and effectiveness.

Under general controls, manufacturers are required to register and to provide an annual listing of the devices made at each manufacturing establishment.

At least 90 days prior to the proposed introduction or delivery of a device for human use into interstate commerce, a manufacturer is required to submit a premarket notification that includes the proposed labeling for the device. If FDA agrees that the device is substantially equivalent to a device in distribution before the Medical Device Amendments were enacted, the device can be marketed. If FDA does not concur in the equivalence, the device is classified in Class III requiring premarket approval. A premarket notification is also required if a manufacturer proposes significant changes in an existing device.

Reports must be furnished to the FDA of deaths or serious injuries that occur in conjunction with the use of any medical devices.

In order for clinical data to be collected to support an application for premarket approval of a device, procedures are provided to exempt the device from certain requirements to permit limited distribution for human clinical use. If the laser medical device emits radiation levels that constitute a significant risk of injury to the patient, formal application and approval by FDA are required before human clinical trials can begin. If the levels are so low as not to constitute a significant risk, the investigation is considered to be approved unless the FDA specifically requires an application. In either case, approval of the investigation by an institutional review board is required.

Regulations published under the Radiation Control for Health and Safety Act of 1968 require manufacturers of laser medical devices to:

- Design and manufacture their devices to comply with the performance standard

Table 3
CUTANEOUS LESIONS THAT MAY RESPOND
TO ARGON LASER THERAPY

- Vascular lesions
  - Port Wine Stains ****
  - Telangiectasia (facial) ****
    - Spider ecstasia
    - Actinic ectasia
    - Chronic radiation dermatitis
      - Associated with CRST syndrome or hereditary hemorrhagic telangiectasia
    - Essential
    - Nasolabial (variable response)
  - Cherry angiomas
  - Adenoma sebaceum ***
  - Rosacea
    - With diffuse erythema and fine ecstasia ***
    - With linear ectatic vessels on nose ****
  - Pyogenic granuloma
  - Capillary hemangiomas (strawberry hemangiomas of infancy)
  - Venous lake ***
  - Lymphangioma ***
  - Kaposi's Sarcoma
  - Granuloma Faciale
- Pigmented
  - Tattoos
    - Decorative
    - Traumatic
  - Melanocytic
    - Cafe-au-lait
    - Lentigines
    - Nevi
    - Giant hairy nevus
    - Lentigo maligna ***
    - Dermal melanocytosis (nevus of Ota)
- Hyperplastic
  - Fibrous papule
  - Rhinophyma *** (Rx with Co_2 laser may reduce blood loss and pain)
  - Seborrheic keratosis
  - Keloids

**** Treatment of choice

*** Results usually better than alternate therapy

- Certify the products
- Test the devices to assure compliance
- Submit reports to the Center for Devices and Radiological Health
- Maintain testing, distribution and safety correspondence records.

The Performance Standard for Laser Products deals only with the laser radiation safety of the device. The standard requires that all radiation not necessary for the device to achieve its intended function must either be eliminated or contained within the protective housing of the device. The level of the radiation to which access is necessary and its associated hazard determines the class of the product. There are four classes. The standard then specifies for each class the degree of controls, indicators and warnings that must be incorporated into the product and its supporting literature.

In addition to the requirements that are applicable to all laser products under the standard, Class III and IV medical laser products are required to incorporate a means for the measurement of the level of laser radiation intended for irradiation of the body. User instructions must include a recalibration procedure and schedule.

Table 4
GLOSSARY OF LASER TERMS

Active Medium: A collection of atoms, ions or molecules in which laser action (stimulated emission) will take place under the proper kind of excitation. The active medium is contained in the laser's optical cavity.

Argon Laser: A laser in which the gas argon is the active medium, after its atoms are ionized by electrical charge. Its beam is in the blue and green visible light spectrum.

Carbon Dioxide Laser: A laser in which CO_2 gas is the active medium. It produces infrared radiation at 10,600 nm.

CW or Continuous Wave: A steadily emitting laser beam, as opposed to pulsed emission. Choice of CW or pulsed emission may be a clinically important decision.

Dye Laser: A laser in which an organic dye dissolved in a solvent is the active medium. Dye lasers emit in the visible light spectrum; some may be "tunable" by adjustments of exciting radiation and dye medium. Often used in conjunction with a photosensitizer such as HPD (see Table 2).

Helium—Neon Laser: A visible light laser in which a mixture of helium and neon gases is the active medium. The gases are usually ionized by a high-voltage, low-current electrical discharge. A He-Ne laser is often used as the "aiming beam" for infrared lasers.

Ion Laser: Any of the lasers that use one of the inert gases (argon, helium, neon, krypton) as the active medium. The gas is ionized by electrical discharge to stimulate laser action.

Irradiance (Power Density): The amount of optical energy incident upon a surface, divided by the area of the surface being irradiated. Usually given as watts per square centimeter.

Krypton Laser: A laser in which the gas krypton is the active medium after ionization by an electric current. Its beam is in the visible light spectrum.

Neodymium: YAG Laser: Usually written as Nd:YAG. A laser in which the active medium is a crystal of yttrium, aluminum and garnet doped with neodymium ions. Its beam is in the near infrared spectrum at 1,060 nm.

Pulse or Pulsed Emission: A pulse is a single, brief, emission of laser radiation. The energy of a pulse is measured in joules (watts times seconds).

Q-Switching: A mode of operating a laser to reduce its pulse and increase its peak power. Laser radiation is released in a short burst of high peak power.

Ruby Laser: A visible light laser in which the active medium is a crystal of aluminum oxide doped with chromium ions. Ruby was the active medium of the first laser.

Wavelength: The distance from crest to crest of an electromagnetic wave, usually given in nanometers (nm) or billionths of a meter. Infrared wavelengths are sometimes given in micrometers (um) or millionths of a meter.

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149th President—Connecticut State Medical Society

Born: Brooklyn, NY, September 24, 1927

Education and Training:
- 1949—Tufts College—B.S.
- 1949-50—University of Connecticut-Graduate School
- 1954—Georgetown University School of Medicine-M.D.
- 1954-55—Internship-Waterbury Hospital, Waterbury, CT
- 1955-56—Residency-Medicine and Pediatrics, Waterbury Hospital

Boards:
- 1970—Diplomate, American Board of Family Practice
- 1976, 1983—Recertified, American Board of Family Practice

Hospital Appointments:
- Waterbury Hospital, Waterbury, CT
  - Attending in Medicine
  - Chairman, Medical Therapeutics Committee
  - Education Committee
  - Executive Committee 1976-78
  - Credentials Committee 1980-
- St. Mary's Hospital, Waterbury, CT 1956-
  - Courtesy Staff
- University of Connecticut School of Medicine, Farmington, CT
  - Advisory Committee, Family Medicine Subject Committee, Family Medicine
  - Clinical Associate in Family Medicine, 1972-75
  - Instructor in Residence 1974-78

Professional Membership and Organizations:

- Waterbury Medical Association, 1957-
  - 1967-70—Secretary
  - 1971—President-Elect
  - 1972—President
  - 1974—Chairman, Public Relations Committee
- Litchfield County Medical Association, 1957-74
- New Haven County Medical Association, 1974-
  - 1976—Board of Governors
  - 1979-80—Vice President
  - 1980-81—President
  - 1980-83—Councilor to Connecticut State Medical Society
  - 1982—Bylaws Committee
  - 1985— Long Range Planning Committee
- Connecticut State Medical Society
  - 1984-85—Vice President
  - 1985—President-elect
  - 1983-84—Vice speaker, House of Delegates
  - 1976—Delegate to House of Delegates
  - 1972—President, Section on Family Medicine
  - 1978—Chairman, Section on Forensic Medicine
  - 1980-84—Chairman Liaison Comm. to D.I.M.
  - 1985—Chairman Liaison Comm. to Medicare (Conn General)
  - 1980—Chairman Liaison Comm. to State Pharmaceutical Association
  - 1975—Public Relations Committee
  - 1975—Malpractice Claims Review Panel
- Amercian Medical Association, 1957-
- Waterbury Academy of Family Physicians, 1957-
  - 1972—President
- Connecticut Academy of Family Physicians, 1957-
  - 1965—Board of Directors
  - 1968-69; 1974-75—Treasurer
  - 1971—President
  - 1969—Chairman, Endowment Fund Scholarship Committee
  - 1971—Chairman, Liaison Committee with Medical Schools
  - 1965-67—Membership and Ethics Committee
  - 1970-71—Recipient, Distinguished Leadership Award
  - 1980—Connecticut Family Doctor of the Year
- American Academy of Family Physicians, 1957-
  - 1975—Delegate, Congress of Delegates
  - 1972—Charter Fellow
  - 1983—Commission on Continuing Medical Education

Activities:

- 1956—Private Practice, Family Medicine, Oakville, CT
- 1970—Fire Surgeon, Watertown, CT
- 1973—Police Surgeon, Watertown, CT
- 1973—Assistant State Medical Examiner
- 1984—State Police Surgeon

Community Service:

- 1972-76—Board of Directors, Watertown Public Health Agency
- 1972—Medical Advisory Committee, Watertown Public Health Agency
  - 1975-77—Chairman
- 1970-83—Medical Director, YMCA Camp, Waterbury
- 1982—YMCA Key Person Award
- Former Chairman, Doctor's Division, United Way, Waterbury
- 1980-81—Commissioner, Connecticut Alcohol and Drug Abuse Commission

The President's Page

Rx: Leadership, Unity and Patient Advocacy

This is my first President's Page, and although the lead time is several months, I want to thank Bill Whalen on behalf of all our members for the magnificant job he has done during the past year.

Our society has taken giant leaps under Bill's direction. The leadership conference was a huge success and will be repeated this year with an expanded guest list. I plan also to continue the meetings between the county presidents and the state officers which Bill inaugurated because cooperation among all levels of organized medicine is clearly tied to any success we may achieve. The feasibility study of a physician-owned and operated statewide IPA/HMO resulted from our President's efforts. By the time this has been published that study will have been completed and the recommendations presented to the House of Delegates for its action. Bill Whalen has represented us well in front of the legislature and other government agencies. He is going to be a hard act to follow!!

I have just returned from the AMA leadership meeting in Washington. This has to be one of the greatest learning experiences for anyone involved in medical association leadership. While there is a certain amount of gloom and doom, I am happy to state that the medical economists, in particular Dr. Uwe Reinhardt, still believe that medicine will survive this period of change and that the practice of medicine will remain rewarding both intellectually and monetarily. He said that he would still encourage his son to enter the field, so I guess he means what he says.

The next clear message that came out of the meeting was the neccessity for medicine to close ranks and act as a unified body. We no longer have the luxury of going off and acting as independent organizations. The time has come to enact unified membership and get everyone in the profession involved. So many of the actions and programs of the AMA benefit us all that it is a shame not to share the cost equally. To mention one program in particular where we all received a benefit is the AMA Reinsurance Company which helped to pick up the slack when other companies pulled back. As Ben Franklin said, "We shall all hang together or assuredly we shall hang separately."

A great deal of the leadership meeting was devoted to alternative health care systems including PPO'S, IPA'S, HMO'S, and joint ventures. I did not sense any superiority of one over another, but that each had its place. Once again, it is comforting to know that our society is one of the first to embark on a possible statewide IPA/HMO venture.

With all the dilemmas we face, it is of the utmost importance that we do not lose sight of the fact that our primary responsibility is to our patient. We must continue to be their advocate and see to it that they receive the best care possible. This statement includes the concept that we must continue the fight to see that improperly trained people are not licensed to provide medical care. Each year, the legislature, based on spurious information, allows more and more medicine to be practiced by non-M.D.'s. As a group, we must stand fast and fight these incursions.

The coming months will be busy. I will attempt to use this column to keep you abreast of the issues.

Joseph C. Czarsty, M.D.
President

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Reflections on Medicine

Be of Good Cheer

ROBERT U. MASSEY, M.D.

Four centuries after Democritus had concluded that the cosmos contained only atoms and void, and made some other observations about the ratio of the volumes of cones and cylinders, pyramids and prisms, Cicero referred to him as the "laughing philosopher" because he had been amused by the follies of mankind, and taught that cheerfulness, *euthymia,* was what ethics was all about.

Osler wrote of himself that he had never mastered philosophy because "cheerfulness was always breaking in." His beloved Sir Thomas Browne had said of heaven that "good natur'd Persons are best founded for that place." Izaak Walton, whom both Osler and his son, Revere, admired, had been known for his cheerful faith. Of his book, *The Compleat Angler,* Charles Lamb had written, "It would sweeten any man's temper at any time to read it."

Recently, in "Sounding Board," Carola Eisenberg,[1] dean for student affairs at Harvard Medical School, took us all to task for talking gloom and lamenting the tribulations of medicine, especially in the presence of medical students. Among ourselves it has become a kind of recreation, each of us competing to describe the future in the deepest shades of stygean black. Pleasurable as the pasttime may seem, sour talk is unhealthy; we should know better than to invite our students to join us.

Rather, wrote Dean Eisenberg, "Let us enlist our students in the campaign for equity and quality in medical care . . . ."

"What we do as doctors most of the time is deeply gratifying . . . . I cannot imagine a more satisfying calling. Let us make sure our students hear that message from us."

Was it easier for Osler to be cheerful? Consider the state of medicine and medical education in North America a century ago. Easier for Browne and Walton? They were loyal to their king, losers in the Civil War, living in the gloomiest of times, Cromwell's Commonwealth.

Democritus' life and times are hazy from this distance, but the century of the Plague of Athens, the Persian and the Peloponnesian Wars, while golden for some, can hardly have brought great contentment to most. Perhaps Democritus laughed at folly from a safe distance.

Just one hundred years ago Theodor Escherich described *Bacterium coli commune* in his monograph on intestinal bacteria in newborns and infants. Forty years ago we were still calling the gram-negative rod *B. coli,* but now to remember this cheerful, enthusiastic pediatrician we speak of *Escherichia coli.* In his brief life of 54 years he converted a provincial Austrian hospital into a model children's teaching clinic, founded a library, set up a laboratory to study diptheria, went on to accept the chair in pediatrics at Vienna, built a new children's clinic, raising much of the money himself, renovated St. Anna's Children's Hospital, and founded the Infant Care Association. He initiated clinical instruction in pediatrics in Vienna, worked to promote breast feeding through an educational center for mothers, and, distressed by high infant mortality rates, used the 60th Anniversary of Franz Josef's reign in 1908 to work for the construction of the Imperial Institute for Maternal and Infant Care. He established and presided over the section of pediatrics in the Viennese Society of Internal Medicine, and founded the Austrian Society for Child Research.

This was a time when intellectuals in the Austro-Hungarian Empire were despairing of liberal Western Civilization; it was an autumnal time of deepening pessimism, and Vienna with its artistic and scientific traditions was caught in the *fin-de-siecle* malaise. But Escherich was bursting with enthusiasm and progressive zeal, full of optimism for the new world which the children were to inherit or build. "Always meticulously dressed," a biographer wrote, "yet genial and approachable, he disliked intrigue or spiteful gossip."[2]

Perhaps he was too prodigal with his energy and cheer for he died of a stroke in February 1911 at the height of his career; surely his students must have remembered him for his good cheer. Like Osler, that may have been his greatest gift; at least, like a good medicine, it could have done them no harm, while gloom is a venom, destroying hope, clogging the mind, and paralyzing action.

REFERENCES

1. Eisenberg C. N Engl J Med 314:1113-4, 1986.
2. Dolman CE, Dictionary of Scientific Biography, Scribner's Sons, NY, IV 403-6, 1971.

ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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Abortion 1986: State Constitutional Perspectives

JOSEPH M. HEALEY, J.D.

The recent struggle over the extent to which abortion is or should be a legally enforceable right in our society has occurred largely in the federal legal system, applying a conceptual framework originally established in the landmark United States Supreme Court cases of 1973.[1] In the intervening thirteen years, a series of subsequent cases has addressed a range of additional issues, including the degree of governmental responsibility for funding abortions. In 1980, for example, the United States Supreme Court upheld congressional action (the Hyde Amendment) limiting reimbursement for the costs of abortion to those situations when the life of the mother would be endangered if the fetus were carried to term (except for such medical procedures necessary for the victims of rape or incest when such rape or incest has been reported promptly to a law enforcement agency or public health services.)[2] In a subsequent case, the Court also held that a state could restrict the payment for abortions to the reimbursement limits provided in the Hyde Amendment.[3] In light of these precedents, advocates of a more extensive role for government funding of abortion have shifted their efforts from the federal court to the state court and from the United States Constitution to state constitutions such as the Connecticut Constitution. In the case of *Doe v. Maher,*[4] a group of indigent women and a group of physicians challenged the legality of a Connecticut policy restricting abortions to those necessary because the life of the mother would be endangered if the fetus were carried to term. In a comprehensive, scholarly opinion likely to engender a great deal of discussion and controversy, Judge Robert Bedron of the New Haven Superior Court has held that the Connecticut policy with respect to funding abortion is violative of the Due Process Clause, the Equal Protection Clause and the Equal Rights Amendment of the Constitution of the State of Connecticut. Unless appealed to a higher court, the *Maher* decision has limited precedential value in its current form. Nonetheless, the issues raised and their treatment by Judge Bedron are of great importance and merit discussion.

In one sense, Judge Bedron didn't need to address the state constitutional dimensions of the funding question. He traced the history of the state's (and colony's) commitment to pay for the medical care of the indigent from 1650, the year of the earliest recorded code in our state, to the present day. He found an unbroken line of more than 330 years of statutory and public policy support for state payment of all necessary medical expenses for the poor. The current Section 17-134b of the General Statutes provides that medical assistance shall be provided for any otherwise eligible person whose income does not exceed the income level permissible under federal law for such eligibility. Judge Bedron rejected all alternative interpretations and concluded that since this statute does not exempt any medical procedure or service for the poor, it must be read in a manner which is consistent with the long-established policy of Connecticut to provide all necessary medical services to those who are eligible. Judge Bedron concluded that the state has no authority to deny funding for medically necessary abortions for this class of poor women.

Ordinarily, this would be the end of the Court's inquiry. The statutory basis for resolving the dispute would eliminate the need for the Court to consider the constitutional issues. Judge Bedron, however, did not stand on this technicality, but identified several reasons why the constitutional issues should be considered in this case. The issues are of great public concern, and to avoid dealing with them would not serve the public interest. Furthermore, if the decision were based solely on statutory interpretation, statutory change might be advanced without the benefit of judicial examination of the underlying constitutional issues. Finally, one issue in damages involves whether the plaintiffs are entitled to attorney's fees incurred on behalf of the class of poor women. To be eligible, the plaintiffs must establish that the defendants violated their constitutional rights. For these reasons, Judge Bedron proceeded to examine the various constitutional claims of the plaintiffs. These will be discussed in next month's column.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

REFERENCES

1. Roe v Wade, 410 US 113, 1973; Doe v Bolton 410 US 179, 1973.
2. Harris v McRae, 448 US 297, 1980.
3. Williams v Zbaraz, 448 US 358, 1980.
4. Rosie J. Doe, et al. v Edward Maher, et al., Superior Court, Judicial District of New Haven, No 196874, April 9, 1986. 12 Connecticut Law Tribune No 17, p 35, 1986.

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Editorials

Stop, Look and Listen:

The CSMS IPA-HMO is Coming

On May 7th, 1986 the House of Delegates voted without dissent that the Society proceed to implement a CSMS statewide IPA-HMO. A Steering Committee has been formed. The Committee is busy refining the recommendations of the feasibility study and action plan submitted to the House of Delegates by the Ad Hoc Committee. Development and management firms are being interviewed, and standards as established by the House of Delegates are being implemented by the Steering Committee. Finally, and most important of all, a statewide educational program for the membership has been developed and will be presented on a scheduled basis during the month. The thirty days of June will be crucial for the success of the project.

In general, most physicians are in support of the CSMS statewide IPA-HMO, but some may be skeptical of its implications because of the lack of information. It is therefore imperative that a direct contact be offered with each and every member of the CSMS during the month of June so that the membership will be in a position to arrive at a prompt and supportive decision. Please read the special insert in this Journal. Do not hesitate to call your CSMS officers, councillors, delegates, or staff, if you wish. Most of all, return the CSMS IPA enrollment form in this Journal, if you have not already responded to the earlier mailing from CSMS.

Protecting Physicians and Patients

There are practical and philosophical implications involved in the decision. From a practical point of view, as repeatedly sermonized, by forging our own organization which is financed, owned, controlled and managed by physicians, profits otherwise to be realized by entrepreneurial intermediaries will be returned to physicians and their HMO, to improve the delivery of patient care and to maintain a competitive edge against the giant cartels poised to enter the State.

In conjunction with the control of CMIC and CPRO, and now an established CSMS IPA-HMO, CSMS physicians will achieve a commanding governance of the vital data. Heretofore, the intermediaries have manipulated the physician because they have been in control of the data. It is of paramount importance for our survival that we obtain the data, own the data, interpret the data, and as a result, make medical decisions which are vital to preserve and protect the interface between physician and patient.

Our potential competitors are anxiously awaiting failure on our part, but your control of CMIC, CPRO, and now a statewide IPA-HMO will demonstrate a formidable combination of strength and staying power to protect us and our patients from exploitation by outside commercial forces.

Making It Happen

Philosophically speaking, in order for this project to succeed, the CSMS membership must be convinced of its necessity for the future of private practice. Not only should we work for its success, but we must be convinced of its value for our patients and our individual members.

The fear of failure always looms nearer and larger than the more distant prospect of success. In the past, many projects have been "strangled by cowardly imagination." The stronger we believe, the more energy we will have at our disposal. We must release the power that comes from belief in ourselves, so that we may ignite our abilities and *make it happen!*

It is time for the membership of the Connecticut State Medical Society to "Stop, Look and Listen." We must *stop* fearing the limitations of the past; we must *look* and abandon the cynicism of the present, and finally we must *listen* to and believe in the long term advantages of a CSMS statewide IPA-HMO. If we do this, and act *now*, we *can* have confidence in the future. We will have designed it ourselves!

William A. Whalen, M.D.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself responsible for statements made by any contributor.

CSMS to Launch Statewide IPA-HMO

The following news release was issued by CSMS on May 22, 1986:

The Connecticut State Medical Society has begun development of the state's first statewide Health Maintenance Organization (HMO). All HMO's now present in the state are local or regional in scope. An HMO is a prepaid medical plan which combines health insurance and comprehensive medical services. The Society aims to recruit a majority of the state's practicing physicians into Connecticut's first statewide Individual Practice Association (IPA). This IPA will in turn develop the statewide HMO, and contract to provide medical and preventive services to it. Other contracts will be negotiated to provide hospital and ancillary services to the HMO's subscribers and their families. The plan will be subject to the approval of the state insurance department, and to state and federal laws relating to HMO's.

The doctors' new plan will be marketed to the state's largest corporations, so that all their employees may have the option of enrolling in it no matter where in the state they are located, and still have their choice of participating primary physicians and specialists alike.

At a time when large outside commercial HMO corporations are poised to enter the state to profit by controlling health care delivery to Connecticut residents, the CSMS doctors' plan is designed to keep the control of health care delivery between physicians and their patients. At the same time, physician panels will monitor its quality and appropriate utilization in accordance with medical standards designed by physicians rather than by insurance companies.

The physicians themselves will capitalize the plan, and also leave a portion of their earned fees in reserve every year to assure its soundness. Patients will have unprecedented choice among providers within the HMO setting, while large employers will have the benefit of "one-stop shopping" for quality HMO coverage for their employees throughout the state. Hopefully, the plan's statewide base will prevent further fragmentation and exploitation of the state's health care system by outside commercial interests. Moreover, its medical sponsorship will assure optimal quality and quantity of care to HMO subscribers.

The savings resulting from economies of scale and medically optimal utilization will be reflected in highly competitive coverage and premium costs for employees and employers. Meanwhile, the physician-patient relationship will not be eroded by the intervention of artifical cost reduction mechanisms based on minimizing care rather than on providing quality appropriate care.

In an HMO whose physicians are at risk for a portion of their fee as well as for their capital investment, the most cost-effective medical care will be state-of-the-art *successful* care and prevention, and nothing less. For patients, it will be just what the doctor ordered.

CSMS IPA/HMO STEERING COMMITTEE

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James P. Orphanos, M.D., (Vice-Chairman) CSMS President-Elect Greenwich	Family Practice
Guy W. Van Syckle, M.D., Chairman of the CSMS Council Danbury	Radiology

IN MEMORIAM

BERNEIKE, ROBERT R., Western Reserve University, 1941. Dr. Berneike was an urologist in the New Haven County area since 1942. He was chief of the urologic service of St. Raphael's Hospital from 1963 to 1980 and associate chief of the section urology of Yale-New Haven Hospital from 1946 to 1963. Before retiring in 1983, he was in the private practice of urology. Dr. Berneike was a member of the New Haven County Medical Assoication, the Connecticut State Medical Society and the American Medical Association; died March 15, 1986 at the age of 70.

CLOONAN, JOHN J., Georgetown Medical School, 1940. Dr. Cloonan was a general surgeon in the Fairfield County area since 1955. He served as chief of surgery at St. Joseph Medical Center from 1967 to 1972. Dr. Cloonan was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 17, 1986 at the age of 70.

FILSON, RALPH M., Queens Medical School, 1915. Dr. Filson was a pathologist. In 1926, he became an assistant medical director at Travelers Insurance Co. in Hartford. He was appointed associate medical director of Travelers in 1944 and medical director in 1949 and in 1956, the medical units were consolidated and he was named chief medical director. Dr. Filson was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 23, 1986 at the age of 94.

GIOBBE, MICHAEL E., Tufts University, 1929. Dr. Giobbe was a general practitioner in the Litchfield County area since 1930. He was associated with Charlotte Hungerford Hospital and retired in 1978. Dr. Giobbe was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Assoication; died February 1, 1986 at the age of 81.

JOSEPH, JULIEN L., Port-au-Prince, Haiti, 1954. Dr. Joseph was an anesthesiologist in the New London County area since 1960. He served on the staff of William W. Backus Hospital for 24 years and for the last two years had been with Norwich Anesthesiology Associates. Dr. Joseph was a member of the New London County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 20, 1986 at the age of 57.

LINDER, JAMES H., College of Physicians and Surgeons, 1927. Dr. Linder was an urologist in the Litchfield County area since 1947. He was associated with Sharon Hospital. Dr. Linder was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Assoication; died February 19, 1986 at the age of 82.

PAPA, JOHN S., Tufts Medical School, 1928. Dr. Papa was an urologist in the Hartford County area since 1928. He served as senior attending surgeon and chief of urology at Bristol Hospital. Dr. Papa was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 2, 1986 at the age of 82.

PARRELLA, LOUIS A., Tufts Medical School, 1934. Dr. Parrella was a general practitioner in the New Haven County area since 1939. He was appointed school physician for the Town of North Haven and served as its police surgeon from 1953 until his retirement in 1984. Dr. Parrella was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 22, 1986 at the age of 76.

RESNICK, JEROME S., University of Pennsylvania School of Medicine, 1959. Dr. Resnick was a neurologist in the Fairfield County area since 1967. He was on the staff of both Stamford Hospital and St. Joseph Medical Center. Dr. Resnick was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died March 27, 1986 at the age of 52.

STEINCROHN, PETER J., University of Maryland, 1923. Dr. Steincrohn was an internist specializing in cardiology in the Hartford County area from 1924 to 1955. He was attending physician at Mt. Sinai Hospital in Hartford for many years and later its chief of staff. Dr. Steincrohn was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died February 18, 1986 at the age of 85.

SUTTON, PAUL, University of Vienna, 1936. Dr. Sutton was a general practitioner in the New London County area since 1943. He was past president of the New London County Medical Association. Dr. Sutton was a member of the Connecticut State Medical Society and the American Medical Association; died February 16, 1986 at the age of 74.

1986 CSMS ANNUAL MEETING HIGHLIGHTS

William D. Logan, Jr., M.D., President of the Medical Association of Georgia, recounts the reasons why M.A.G. established its physician-owned, statewide IPA-HMO.

Joseph C. Czarsty, M.D., Oakville Family Physician, addresses the House of Delegates after being installed as the 149th President of the Society.

William A. Whalen, Jr., M.D., Willimantic, presents $200 checks and appropriately inscribed plaques to Hanna Henry of Hartford (junior division) and Nathan Perry of Putnam (senior division) who were first place winners of the CSMS awards for academic excellence in this years' Connecticut Science Fair.

Reference Committee One listens to testimony on the CSMS statewide IPA-HMO. (l. to r.) W. Raymond James, M.D., Essex, chairman; Neil C. Klein, M.D., Stamford; Theodore Zanker, M.D., New Haven; and Howard Wetstone, M.D., Hartford.

William A. Whalen, Jr., M.D., Willimantic, 148th president, administers the oath of office to incoming president, Joseph C. Czarsty, M.D. of Oakville.

Lawrence B. Ahrens, M.D. of Newington, Speaker of the House of Delegates, chairs the 194th annual meeting of the Society as Josephine Lindquist, Associate Executive Director, and Tim Norbeck, Executive Director, look on.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511 Telephone 865-0587

Timothy B. Norbeck, *Executive Director*

Josephine P. Lindquist, *Associate Executive Director*

Raymond T. Sullivan, Jr.
Assistant Executive Director
Public Affairs

Robert J. Brunell
Assistant Executive Director
Scientific Activities

Shelley A. Marcus
Director of
Government Relations

SUMMARY OF PROCEEDINGS CSMS HOUSE OF DELEGATES—ANNUAL MEETING May 7, 1986 — NEW HAVEN

Reports and Addresses

The House received reports, addresses and/or remarks from the President, Secretary, Treasurer, the Council, Delegates to AMA, Chairman of the Board of Directors of COMPAC, the Executive Director, the President-Elect of the Auxiliary to CSMS, Connecticut Medical Insurance Company, Standing Committees, Representatives and Advisors, and the delegates from Massachusetts, Vermont, New Jersey, and New York.

Election of Officers and Others

The House voted to approve the published report of the Nominating Committee (the Council) with minor amendments. Officers elected were:

President: Joseph C. Czarsty, M.D., Oakville
President-Elect: James P. Orphanos, M.D., Greenwich
Vice-President: Norman A. Zlotsky, M.D., Rockville
Secretary: Annemarie S. Welch, M.D., New Britain
Treasurer: Robert R. McDonnell, M.D., New Haven
Speaker of the House of Delegates: Lawrence B. Ahrens, M.D., Newington
Vice-Speaker of the House of Delegates: Mehdi S. Eslami, M.D., Waterbury

Three Delegates and three Alternate Delegates to the AMA for the term January 1, 1987 to December 31, 1988. (Terms of two other delegates do not expire until December 1987).

Guy W. Van Syckle, M.D., Danbury (D)
William A. Whalen Jr., M.D., Willimantic (A)
Frank K. Abbot, M.D., Hartford (D)
Jerome K. Freedman, M.D., New Haven (A)
Stewart J. Petrie, M.D., Derby (D)
Joseph S. Sadowski, M.D., Hartford (A)

Councilor-at-Large: Joseph S. Sadowski, M.D., Hartford

Summary of Actions Taken

All items of business not calling for specific action by the House were accepted directly for filing. Items calling for action to be taken by the House of Delegates were heard by reference committees and based on the reports of the reference committees were acted on as follows:

Committee Membership

VOTED to increase the membership strength of four committees as follows:

Committee on Continuing Medical Education—20 to 25
Editorial Committee of Connecticut Medicine—15 to 20
Committee on Legislation—20 to 25
Committee on Medical Aspects of Sports—20 to 25

Statewide IPA/HMO

VOTED to approve the following recommendations:

1. That CSMS proceed to implement a CSMS statewide IPA-HMO as recommended by the Council.
2. That a steering committee be elected by the CSMS Council after consultation and nominations from the county associations.
3. That the steering committee be charged to interview and recommend a development and/or management consultant to the CSMS Council for its approval.
4. Standards for the steering committee:
    a. CSMS shall not suggest or infer that doctors not participate in other IPA's and/or HMO's.
    b. We shall undertake serious discussions with other IPA's, HMO's, MDS's, and county medical associations.
    c. CSMS shall go through counties for county representatives for development, marketing, and other issues.
    d. We shall, if at all possible, find alternative QA and UR mechanisms and educational programs to replace gatekeeper or case manager mechanisms.
    e. HMO stock is to be owned only by physician participants of CSMS IPA.
    f. The steering committee shall with sensitivity review questions of regional differentials.
    g. Steering committee shall be sensitive to benefit discrimination by specialty.
    h. We shall be provided a legal structure to assure a continued CSMS role in IPA/HMO management and policy.
    i. The committee shall make regular reports to the CSMS Council.

Nursing Home Visitation and Regulations Punishment of Physicians by the Medicare Program

Action taken by the AMA Council on Medical Services on these subjects were presented to the House of Delegates.

VOTED to accept items 1 and 2 below as information:

1. **Nursing Home Visitation and Regulations**
   "The AMA Council on Medical Services recently recommended the following AMA positions (Report F 1-85):
   - a. The AMA should seek changes in the "Conditions of Participation for Skilled Nursing Facilities" so that a little flexibility in physician visitation requirements might result. Specifically a five day leeway was mentioned.
   - b. The AMA should seek more flexibility in the Medicare regulations concerned with drug and treatment orders in SNF's.
   - c. The AMA should encourage state medical societies to work with state legislatures and regulatory bodies to modify state regulations to match the federal ones.

   The Council reached these conclusions after review of the federal requirements, discussions with the Wisconsin and New York State Medical Societies which sponsored resolutions that began the Council's activity and discussions with Health Care Financing Administration representatives."
2. **Punishment of Physicians by the Medicare Program**

"When the Federal Department of Health & Human Services applies monetary penalties and/or suspension from the Medicare Program, to a physician, the physician's legal remedies are limited. As the regulations are written now, all the physician can do apparently is to ask the U.S. Court of Appeals to review the record as a whole. Judicial review is restricted to whether the facts alleged appear to be backed by substantial evidence in the record as a whole.

Since there is no opportunity for a trial by jury, the Texas Delegation to the AMA in R 93 (1-85) asked the AMA to attempt to have Congress amend the Social Security Act to permit a trial *de novo,* when penalties exceed $10,000 and/or when a suspension from the Medicare Program is ordered."

VOTED that the Council of CSMS continue to pursue nursing home change in visitation regulations of HCFA to resolve the present cruel "Catch 22" dilemma of retrograde denial.

VOTED that the AMA delegation at the annual meeting of the AMA House of Delegates support all efforts to pursue the full implementation of items 1 and 2.

Nominations of Directors of CMMI (Connecticut Medical Management Incorporated)

VOTED to approve the election of the following to serve as directors of CMMI: Drs. Jerome K. Freedman, W. Raymond James, Sultan Ahamed, Daniel W. Doctor, Kevin W. Dowling, Mehdi S. Eslami, James P. Orphanos, Joseph S. Sadowski, and Mr. Timothy B. Norbeck.

Resolutions Re Election of CMMI Directors and CMMI Bylaw Changes

VOTED to approve the following resolutions:

RESOLVED: That the Council shall nominate and the House of Delegates select a slate of directors for vacancies in the CMMI Board of Directors in the same manner and at the same time as officers of the Society are nominated and elected. The directors to be nominated and elected by the CSMS at the annual meeting of the CMMI.

RESOLVED: That Society approval of CMMI bylaw changes shall require two-thirds majority of delegates present and voting in a duly called meeting of the House of Delegates. The call of the meeting shall include copies of the proposed bylaw changes.

RESOLVED: That the President of CSMS be authorized to act as shareholder on behalf of CSMS at the annual meeting of CMMI.

RESOLVED: That Section 2.01 of Article II of the Bylaws of Connecticut Medical Management, Inc. be revised to read as follows:

Section 2.01 Annual Meetings: The annual meeting of shareholders, for the election of Directors and for the transaction of any other business relating to the affairs of the Corporation which may come before the meeting, shall be held annually on such date, within the first six months of each year, as the Board of Directors shall designate.

Proposed Amendment to the Bylaws

The following amendment to the Bylaws was placed on the table for action at the next regular meeting of the House of Delegates.

Subject: Dues for New Members

OBJECTIVE: To reduce the dues of all new members who are elected in the spring to one-half of the annual dues.

PROPOSED AMENDMENT: Article XII—Dues

Section 1: Prescription—(Add words in capitals)

Par. 1—Annual dues for Active Members shall be prescribed for the ensuing fiscal year in an amount recommended by the Council and approved by the House of Delegates and shall be an equal per capita assessment upon each Active Member except that physicians who become Active Members during the SPRING WILL BE ASSESSED ONE-HALF OF THE ANNUAL DUES FOR THAT FISCAL YEAR AND PHYSICIANS WHO BECOME ACTIVE MEMBERS DURING the latter half of a fiscal year will be assessed one-quarter of the annual dues for that fiscal year.

NEW MEMBERS

FAIRFIELD COUNTY

Charles Augenbraun, M.D., Westport
Bharati K. Banerjee, M.D., Stamford
Donald L. Butler, M.D., Easton
David M. Chess, M.D., Stratford
Jack S. C. Fong, M.D., Danbury
Arnold W. Forrest, M.D., Wilton
Louis A. Fuoco, M.D., Noroton
Jonathan G. Greenwald, M.D., Norwalk
Katherine P. Holden, M.D., Norwalk
Kathy L. Lesser, M.D., Stamford
Robert A. Lindberg, M.D., Stamford
Patrick D. McBroom, M.D., Easton
Gianfranco U. Meduri, M.D., Norwalk
Nicholas J. Messina, III, M.D., Stamford
Robert B. Miller, M.D., Westport
Thomas D. Olsavsky, M.D., Fairfield
Arthur C. Pinto, M.D., Westport
Edward A. Prior, M.D., Stamford
James P. Ralabate, M.D., Stratford
Harvey L. Ryback, M.D., South Norwalk
Pushpa N. Shah, M.D., Shelton
Cindy S. Sheets, M.D., West Haven
Richard C. Sheinbaum, M.D., Stamford
Robert J. Stiller, M.D., Bridgeport
Margaret E. Sweeney, M.D., Norwalk
Florentine Thomas, M.D., New Haven
Diane D. Wirz, M.D., Danbury

HARTFORD COUNTY

Steven A. Belinkie, M.D., Hartford
Peter J. Beller, M.D., Hartford
John T. Cardone, M.D., Hartford
James W. Cox-Chapman, M.D., Bloomfield
Alfred G. Gladstone, M.D., New Britain
Francis J. Kiernan, M.D., Hartford
Michael L. Krall, M.D., Hartford
Stuart K. Markowitz, M.D., Hartford
Nalini M. Pathiyal, M.D., Hartford
Gerald P. Pierre, M.D., Bloomfield
Anne E. Pinou, M.D., Hartford
Milton J. Sands, M.D., New Britain
James T. Sayre, M.D., Bristol
Robert J. Schwartz, M.D., Hartford
Nazek R. Shabayek, M.D., Southington
William B. Spector, M.D., Bloomfield
Judith A. Stein, M.D., Rocky Hill
Charles F. Stroebel, M.D., Hartford
Robert R. Toscano, M.D., Bristol
Jean M. Weigert, M.D., New Britain

LITCHFIELD COUNTY

Mary Jane Brackett, M.D., Watertown
Joel A. Danisi, M.D., Kent
Eugene Moskowitz, M.D., Salisbury
Jeffrey A. Sanderson, M.D., Bridgewater
Jan D. Silberstein, M.D., Torrington

NEW HAVEN COUNTY

Harry A. Ardolino, M.D., Branford
Michael M. Bakerman, M.D., Meriden
William E. Braisted, M.D., Branford
Malcolm Brochin, M.D., New Haven
Daniel W. Chin, M.D., Milford
Janis Cooley-Jacobs, M.D., Hamden
Gary J. Dee, M.D., Meriden
Pasquale J. DeMatteo, D.O., New Haven
Alan R. Ecker, M.D., Madison
Claudette V. Engle, M.D., Madison
James H. Farmer, M.D., New Haven
Michael A. Feinberg, M.D., Waterbury
Mark J. Goldstein, M.D., New Haven
Barry R. Hansen, M.D., Shelton
Charles B. Helm, M.D., Wallingford
Thomas J. Helm, M.D., Wallingford
Delbert H. Hodder, M.D., Waterbury
Steven S. Jacoby, M.D., New Haven
Clifford R. Kramer, M.D., New Haven
Anthony L. LaBruzza, M.D., New Haven
Anthony T. LaMarca, M.D., Milford
Kathleen A. Ljungquist, M.D., Cheshire
Richard W. Long, M.D., New Haven
Thomas F. Milligan, M.D., Guilford
James L. Novick, M.D., New Haven
Marguerite S. Rao, M.D., Branford
Marcia F. E. Satlow, M.D., Southbury
Richard J. Sorcinelli, M.D., Hamden
Andrew C. Wormser, M.D., New Haven
Neal J. Zimmerman, M.D., Waterbury

NEW LONDON COUNTY

Timothy Barczak, M.D., New London
Ganpat Chouhan, M.D., Uncasville
Edward Coss, M.D., New London
Peter Famiglietti, M.D., Waterford
Lucinda Hautaniemi, M.D., Old Lyme
Ann Jillson, M.D., Norwich
Mark Kropf, M.D., New London
Frank Maletz, M.D., Groton
Naomi Nomizu, M.D., New London
Charles Parrot, M.D., New London
Douglas Roberts, Jr., M.D., Old Lyme
Henry Rose, M.D., New London
Vijaya Sikand, M.D., Old Lyme
Timothy Sullivan, M.D., Norwich
Roger Van Dyke, M.D., Groton

TOLLAND COUNTY

Dush Parikh, M.D., Somers
Ravindra N. Vajjhala, M.D., Rockville
Wayne D. White, M.D., Rockville

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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

AMBULATORY CARE

Position open full or part-time for physician for ambulatory care center in Enfield, CT. Contact Richard Stevens, M.D., Medical Director, 15 Palomba Dr., Enfield, CT. (203) 745-1684.

GENERAL PRACTICE

Licensed physician for full or part time. Send CV to Dr. Schlessel, 100 Broadway, North Haven, CT 06473.

Physician wanted for part time work in shoreline general practice. Experience in general practice or internal medicine essential. No night or hospital work. Inquiries can be made to Dr. R.J.N. Keer, M.D., P.O. Box 338, Clinton, CT 06413.

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Obstetrician/Gynecologist, BE/BC, to join established two doctor OB/GYN private practice in Hartford area of Connecticut. Major teaching hospital affiliations. Excellent salary and benefits including paid professional liability and health insurance, with progression to partnership. Send CV to CSMS, c/o OB/MM.

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Pediatrician, BC/BE to share practice with another pediatrician in a progressive community health center in New Haven, CT. Seeking an individual to work in a challenging and rewarding community health setting who will be part of a primary care team. In addition to clinical practice, position includes hospital responsibilities and call. Spanish-speaking helpful. Contact, Katrina Clark, MPH, Director, Fair Haven Community Health Clinic, 374 Grand Ave., New Haven, CT 06513. (203) 777-7411.

Seeking second Neonatologist for July '86 as a 400+ bed, Central Connecticut General Hospital. University of Connecticut affiliate. Responsibilities to include clinical care in busy, Level II nursery and implementation of planned expansion to designated Level II unit in regional program. Interest in management of older, acutely ill children desirable. Ample opportunity for teaching and research interests. Direct inquiries to A. M. Capriglione, M.D., Chief of Pediatrics, New Britain General Hospital, 100 Grand St., New Britain, CT 06050.

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EMERGENCY MEDICINE

Sept. '87. Age 41. Presently in practice. FLEX. AB elig. MD, Meharry Medical College, Nashville, TN. Int., Hubbard Hospital, Nashville; Res., Hubbard Hospital (General Surgery). Prefers institutional type practice in a large-sized community. Write, William T. Carter, Jr., M.D., 2252 MCDEC Quantico, VA. 22134.

GENERAL PRACTICE

Availability negotiable. Licensed in Connecticut. Age 34. Nat'l bds. AB cert. MD, UConn, Farmington; Int., Griffin Hospital, Derby; Res., Conn. Valley Hospital, Middletown. Also interested in psychosomatic medicine and rehabilitation medicine. Prefers group, associate, institutional or industrial type practice. Write, P.O. Box 239, Higganum, CT 06441.

INTERNAL MEDICINE

July '86. Age 30. Nat'l bds. AB cert. MD, S.U.N.Y., Downstate Medical Center, Brooklyn, NY: Int. and Res., Kings County, Downstate, (Brooklyn VA Hospital); Fellowship, Nassau County Medical Center (Gastro), NY. Seeking position as associate/partner in small group. Fully trained in all routing endoscopic procedures. Write, Frank J. Karpowicz, M.D., 200 Carman Ave., Apt. 8C, East Meadow, NY 11554.

July '86. Age 34. AB elig. MD, Guntur Medical College, India; Int., Government General Hospital, India; Res., V.A. Medical Center, Wilkes-Barre, PA. Prefers solo, group or associate type practice in a medium-sized community. Write, R.R. Makkena, M.D., 501 Indian Creek Dr., Wilkes-Barre, PA 18702.

July '86. Age 27. FLEX. AB elig. MD, Universidad Central del Este, Dominican Republic; Int. and Res., St. Joseph's Hospital, Paterson, NJ. Desires solo or associate type practice. Write, Roger Steinfeld, M.D., 100 Hospital Plaza, Apt. 807, Paterson, NJ 07503.

July '86. Age 31. Presently in practice. Nat'l bds. AB elig. MD, New York Medical College; Int. and Res., Montefiore Medical Center. Prefers group or associate type practice. Write, Joseph Cohen, M.D., 16 Mountainbrow Townhouse, Corning, NY 14830.

July '86. Age 30. Nat'l bds. AB elig. MD, Northwestern Medical Center, Chicago, IL; Int. and Res., Northwestern University (McGraw Medical Center). Prefers a group type practice in a small to medium-sized community. Write, Stephen M. Spear, M.D., 215 E. Chicago Ave., Apt. 2305, Chicago, IL 60611.

July '86. Age 33. Licensed in Connecticut. Nat'l bds. AB cert. MD, Georgetown University; Int. and Res., New England Deaconess Hospital; Fellowship, Yale University, New Haven. Prefers group, associate or institutional type practice in a large-sized community. Write, Dean F. Markham, Jr., M.D., 815 Whitney Ave., #5, New Haven, CT 06511.

ALLERGY. Immediately available. Age 43. Licensed in Connecticut. Nat'l bds. AB elig. MD., Temple University School of Medicine; Int., Beth Israel Hospital New York, NY; Res., University Hospital, Ann Arbor, Michigan; Fellowship, Albert Einstein Medical Center, Philadelphia, PA. Wishes to relocate part time or full time near Weston, CT. Write, Harold Axe, M.D., 25 Fifth Ave., New York, NY 10003.

ENDOCRINOLOGY. March '87. Age 30. Nat'l bds. AB cert. MD, McGill University, Montreal, Canada; Int. and Res., Johns Hopkins Hospital, Baltimore, MD; Fellowship, MRC Neurochemical Pharmacology Unit, Cambridge, England and Johns Hopkins Hospital. Prefers a group type practice. Especially interested in HMO-based practice with part-time affiliation with a teaching hospital. Write, Helene M. Langevin, M.D., 2241 Rogene Drive, Apt. T2, Baltimore, MD 21209.

NEPHROLOGY. Available July '86. Age 52. Licensed in Connecticut. FLEX. AB elig. MD, Universidad Autonoma de Cd. Juarez, Mexico; Int. and Res., Lincoln Medical Center, Bronx, NY; Fellowship, Booth Memorial Medical Center, Flushing, NY. Would be interested in working in emergency room, critical care or primary care settings in a medium to large-sized community. Write, Olga F. Szabo, M.D., 351 East 84 St. Apt. 23B, New York, NY 10028.

NEUROLOGY

July '86. Age 30. AB elig. MD, Int. and Res., S.U.N.Y. Stony Brook, NY. Prefers group, associate or institutional type practice in a medium to large-sized community. Currently Assistant Professor of Neurology, Temple University. Write, Richard M. Hassett, M.D., 11 N. 2nd Street, Apt. 201, Philadelphia, PA 19106.

Sept. '86. Age 34. FLEX. AB elig. MD, University of Bombay, India; Int., Grant Medical College, Bombay; Res., University of Tennessee, Memphis, TN. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Kirit C. Shah, M.D., 50 S. Morrison, Apt. #7, Memphis, TN 38104.

PATHOLOGY

Board certified Pathologist, AC-CP, available in Connecticut for Locum Tenens or part-time position. Please phone (203) 224-5584.

Sept. '86. Age 38. Licensed in Connecticut. Presently in practice. Nat'l bds. AB cert. MD, University of North Carolina; Int. and Res., Rhode Island Hospital, Providence, RI; Res., (Path) Yale New Haven Hospital. Prefers solo, group, associate or institutional type practice. Write, Richard N. Pierce, M.D., 14313 Piccadilly Rd., Silver Spring, MD 20906.

PEDIATRICS

Immediately available. Age 43. Presently in group practice. FLEX. AB cert. MD, University of Ceylon; Int., Methodist Hospital, Brooklyn, NY; Res., Downstate Univ./Kings Co., Brooklyn, NY; Fellowship, Coney Island Hospital, Brooklyn, NY. Prefers group, associate or institutional type practice. Write, Michael A. Satchie, M.D., 4220 Patzke Lane, Racine, WI 53405.

PLASTIC SURGERY

July '87. Age 30. Nat'l bds. AB elig. MD, University of Chicago, Chicago, IL; Int. and Res., University of Michigan, Ann Arbor, MI; Fellowship, Hospital of the University of Pennsylvania, Philadelphia, PA. Seeking private practice with/or University affiliation in a large-sized community. Write, Jerrold Zeitels, M.D., #16, 240 East Montgomery Ave., Ardmore, PA 19003.

PRIMARY CARE

Feb. '86. Age 33. AB cert. MD, University of Rome, Rome, Italy; Int., Long Island College Hospital, Brooklyn, NY; Res., Illinois Masonic Medical Center, Chicago, IL. Prefers group, associate or HMO type practice in a medium-sized community preferably in western Connecticut. Write, Eli R. Goldner, M.D., 2841 West Rosemont, Chicago, IL 60659.

PSYCHIATRY

Immediately available. Age 59. Licensed in Connecticut. Presently in practice. AB cert. MD, London University, England; Int., Bridgeport Hospital, Bridgeport; Res., Cornell University, NY; Fellowship, National Neurological Hospital, London, England. Prefers part time employment in a medium-sized community. Write, Colin B. Cook, M.D., 373 Strawberry Hill Ave., Stamford, CT 06902.

RADIOLOGY

Feb. '86. Age 45. Licensed in Connecticut. Nat'l bds. AB elig. MD, Odessa Medical Institute, USSR; Int., Medical Institute's Hospital, USSR; Res., Bridgeport Hospital, Bridgeport, CT; Fellowship, University of Connecticut Medical Center, Farmington, CT. Has a specialty in Nuclear Medicine and Nuclear Cardiology. Has no preference to type of practice or size of community. Write, Michael Sedlovsky, M.D., 191 Barry Scott Dr., Fairfield, CT 06430.

Immediately available. Age 59. Licensed in Connecticut. Nat'l bds. AB cert. MD, Georgetown University School of Medicine; Int., St. Francis Hospital, Hartford, CT; Res., Temple University Hospital, Philadelphia, PA. Seeking part time, perdiem, or full time position in Diagnostic Radiology. Write CSMS c/o JRG/RAD.

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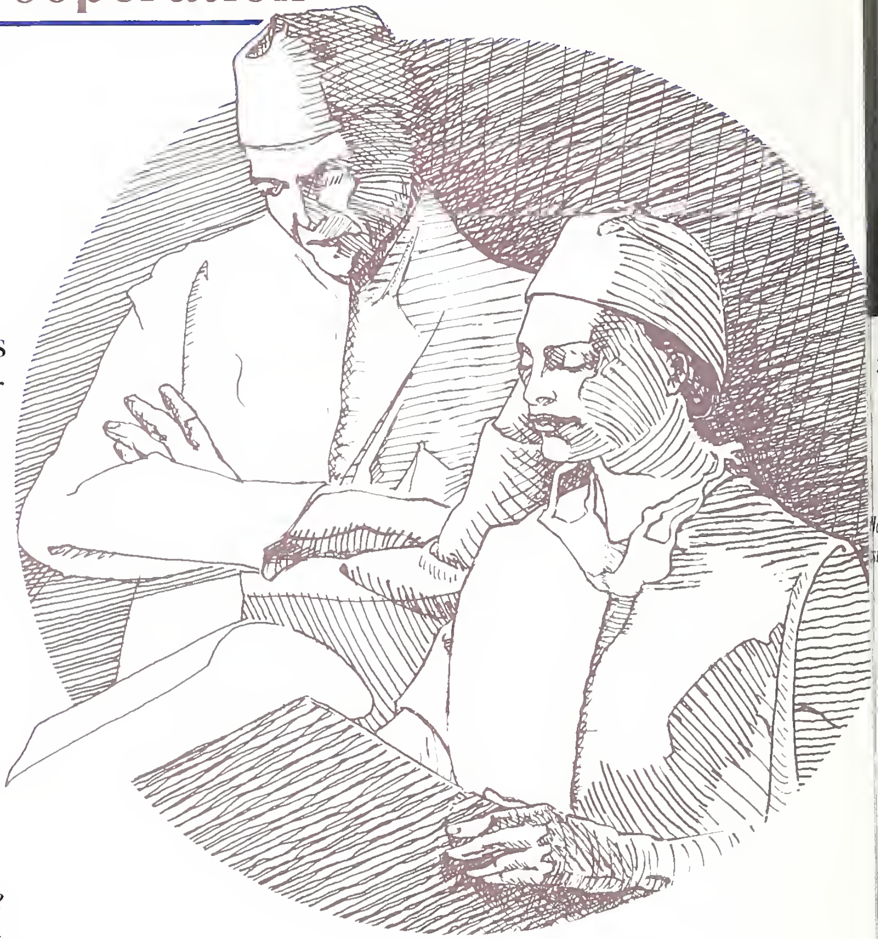

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Cardiac Transplantation: First Year Experience at Hartford Hospital

JAMES E. DOUGHERTY, M.D., F.A.C.C., ALFREDO F. NINO, M.D., F.A.C.C., MICHAEL A. ROSSI, M.D., F.A.C.C., HENRY B. C. LOW, M.D., ROBERT T. SCHWEIZER, M.D., STANLEY A. BARTUS, M.D., HIROYOSHI TAKATA, M.D., A. DAVID DREZNER, M.D. AND JAMES J. GALLAGHER, M.D.

ABSTRACT— Cardiac transplantation has clearly become an accepted therapy for selected patients with end-stage heart disease.[1,2] With appropriate screening of both donor and recipient, coupled with rigorous post-operative management and follow-up, the survival results after orthotopic heart transplantation continue to improve. The first heart transplant operation at Hartford Hospital was performed in November, 1984, and over the following one year period a total of ten such operations have been performed. All ten patients are clinically doing well and remain functional New York Heart Association (N.Y.H.A.) Class I. Specific aspects of this patient group, donor and recipient selection criteria, surgical technique and post-operative management are reviewed in detail.

Since the introduction of cardiac transplantation in December, 1967, more than 1500 transplant procedures have been performed worldwide.[3,4] The majority of these operations have been completed in the past several years. In 1984, twenty nine transplant centers in the United States performed approximately 300 transplant procedures. This number is estimated to have grown to 90 centers in 1985. The exponential growth of both the number of operations performed and the increased survival can be attributed to a better understanding of cyclosporine immunosuppression and the role of surveillance right ventricular endomyocardial biopsy. The present renaissance in cardiac transplantation is further supported by the 1- ,3- and 5-year survival rates which at present exceed 80%, 70% and 55+% respectively, with the suggestion that they may yet improve further.[5]

Indications and Recipient Selection

Patients being considered for orthotopic cardiac transplantation suffer from terminal heart disease with an expected survival of less than one year if not transplanted. Virtually all patients are progressive N.Y.H.A. Class III or Class IV disability secondary to ischemic left ventricular dysfunction or idiopathic cardiomyopathy. (Table 1) No absolute age restrictions have been established at our institution, instead the overall perspective of the transplant candidate relative to his or her potential for rehabilitation and functional recovery is used by the transplant team to help determine candidacy.

Specific exclusion criteria from transplantation have been previously reviewed.[6] In addition to these, a thorough in-hospital evaluation is performed upon all patients being considered for transplant candidacy. This generally includes endomyocardial biopsy and right heart catheterization. The presence of elevated and fixed

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pulmonary vascular resistance (PVR) exceeding four to six Wood units is now recognized as a contraindication to transplantation.[6] All of our patients undergoing transplantation had dynamic pulmonary vascular resistance of ≤ 2.5 Wood units. No patient undergoing transplant was diabetic, however, in the absence of advanced microangiopathic or peripheral vascular disease, diabetes mellitus is not felt to be a contraindication to transplant surgery.

Table 1
HARTFORD HOSPITAL TRANSPLANTATION POPULATION

#	*Patient*	*Age*	*Transplant Date*	*Diagnosis*
1	A.B.	35	11/84	Ischemic
2	A.K.	39	2/85	Cardiomyopathy
3	G.H.	52	3/85	Cardiomyopathy
4	M.S.	38	5/85	Cardiomyopathy
5	R.M.	39	5/85	Cardiomyopathy
6	L.M.	55	6/85	Ischemic
7	E.H.	55	8/85	Cardiomyopathy
8	R.D.	33	8/85	Cardiomyopathy
9	L.S.	58	10/85	Ischemic
10	W.R.	58	11/85	Ischemic

During the first year, thirty two patients were referred for possible transplantation. Of these, ten underwent cardiac transplantation, four are actively awaiting transplantation, and five are alive but felt to be premature for transplant consideration. The remaining thirteen patients died, most within a few days of referral. These statistics reflect the stringent selection criteria utilized and support the fact that in the absence of transplantation the survival rate is poor for this patient population. Referral at too advanced a stage may preclude the chance for a heart transplant.

Donor Procurement

Organ availability remains the limiting factor for the future growth of cardiac as well as other extra-renal transplantation. While there are estimated to be in excess of 20,000 "brain-dead" potential donors, only 500 hearts will be reimplanted in the United States this year.[7] One-third of end-stage cardiac patients who would benefit from transplantation and who have passed the necessary medical and financial hurdles will die awaiting surgery, a number which almost certainly will grow. The problem has the potential of becoming of crisis proportions as the process of heart transplantation matures and the immunosuppression improves.

Of the ten patients undergoing transplantation in our series, four received Connecticut donor organs. Six donor organs were obtained using long distance procurement techniques.[8] (Figure 1). This is coupled with the fact that the Hartford Organ Retrieval Program has for many years sent extra-renal organs out of state utilizing the North American Transplant Coordinators Organization (NATCO). The combination of a regional organ donor pool plus a positive working relationship within the NATCO computer system will help to provide a solid future base of donor organs for the future.

Surgical Technique

The original surgical technique of Lower and Shumway remains largely unchanged and is the technique utilized in our program.[9] Details of the operative procedure have been previously described and remain unchanged.[6] Minor modifications involving cardioplegic arrest have evolved which have greatly improved the ease with which the transplanted donor organ develops its own automaticity once again. Hemostasis remains a major surgical concern in view of the several long suture lines along the atria. Fortunately, careful attention to surgical detail has resulted in only one patient with increased post-operative bleeding and this subsequently proved to be only a minor problem.

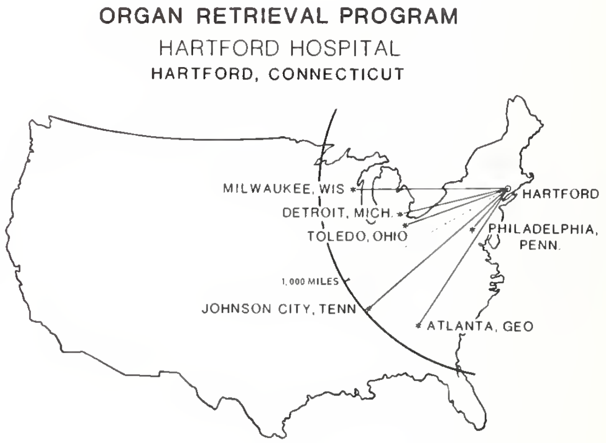

Figure 1

Graphic representation of the varying locations and relative distances for heart procurement at Hartford Hospital.

Post-Operative Management

Following a brief period of observation in the recovery room, the patient is taken to the surgical intensive care unit where he or she is maintained in reserve isolation. Dopamine and isoproterenol infusions are started in the operating room and titrated over the first seventy two hours post-operatively to increase the inotropic and chronotropic abilities of the transplanted heart.[10] As noted previously, the transplant patient is unique in that each has two sinus nodes—the old and the new.[6] The ability of these two electrical pacemakers to show discordant rhythms has been known, but we have been able to study and document this phenomenon further with intracardiac HIS Bundle electrocardiography. One of our patients had underlying atrial flutter which then persisted post-transplantation (Figure 2). To document that the donor organ was in fact in sinus rhythm and that the surface ECG was largely reflecting remnant atrial activity, HIS recordings were obtained (Figure 3). High and low atrial recording catheters clearly documented ongoing stable atrial flutter secondary to the remnant atrium with sinus rhythm in the donor heart being the active cardiac rhythm.

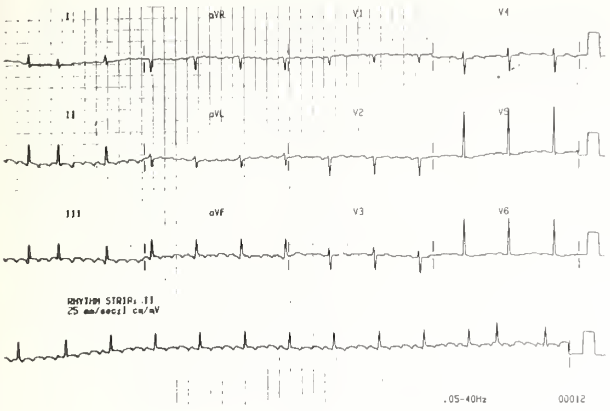

Figure 2

Standard twelve lead electrocardiogram showing underlying atrial flutter as the apparent dominant rhythm. However, electrophysiologic studies have shown this rhythm is in fact normal sinus with P waves which are best demonstrated in the rhythm strip of lead II.

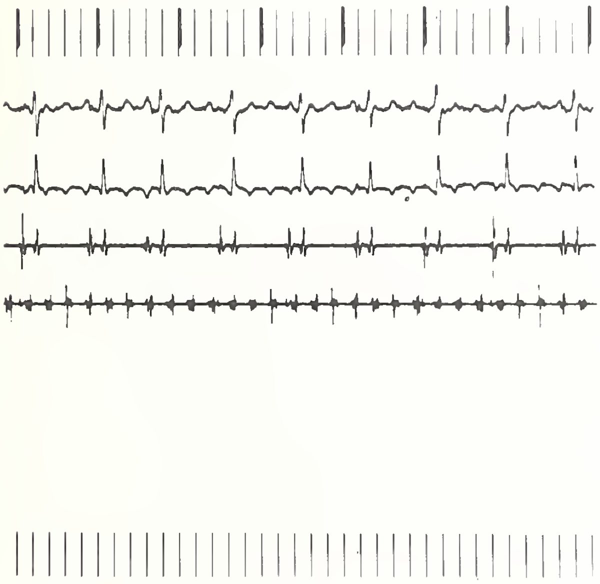

Figure 3

Four channel electrophysiologic study (EPS) depicting standard EKG's on lines one and two and HIS catheter studies on lines three and five outlining clear cut flutter dissociation from the standard HIS bundle tracing.

Right ventricular endomyocardial biopsy remains the only sensitive and specific means for diagnosing acute allograft rejection.[11] The increased use of cyclosporine makes this technique even more important since the clinical expression of rejection is largely absent in the presence of this agent. Prospective studies at our institution and elsewhere are ongoing to help develop an acceptable non-invasive adjunct to biopsy to diagnose rejection in its early phases. Biopsies are performed weekly over the first six to eight weeks and on a decreasing periodicity thereafter. Lifelong surveillance biopsies are performed three to four times per year thereafter. The technique and methodology utilized was developed by Caves et al in 1973 with access obtained via the right internal jugular vein (Figure 4).[12,13] Biopsies have been performed from the left neck and the femoral vein, but each of these approaches has inherent inadequacies.

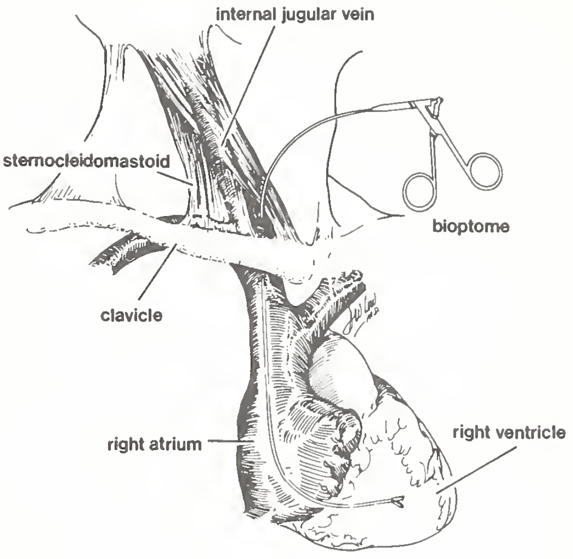

Figure 4

Graphic depiction of right internal jugular cannulation and access for right ventricular endomyocardial biopsy. The biopsy jaws are positioned in the right ventricle at the lower medial septum.

Infection continues to account for a significant amount of the morbidity and mortality following cardiac transplantation.[14] It is anticipated that the use of triple immunosuppression with reduced cyclosporine, azathioprine and prednisone will favorably impact upon both the number and severity of post-operative infections. A total of three infections occurred in two patients as outlined in Table 3. An aggressive and invasive diagnostic and then empiric therapeutic approach was employed in each of these infections. No major morbidity ensued and all subsequently cleared with conventional therapy. Increased surveillance biopsies were employed at the time of infection because of the recognized association of infection and rejection.

Optimal immunosuppression remains the single most important element in the successful management of patients undergoing cardiac transplantation. Cyclosporine has both improved survival results and reduced the severity of infection secondary to immunosuppression Cyclosporine first became available for clinical trials in 1979 and was approved by the Food and Drug Administration in November, 1983.[15] At that time it was incorporated into our renal transplant program and, from its inception, has been combined with azathioprine and prednisone to form the basis of triple immunosuppression in our cardiac program (Table 2). This combined regimen has resulted in reduced infection, reduced renal dysfunction and reduced probability of longer term nephrotoxicity secondary to cyclosporine (Table 3).[16]

Table 2
CURRENT IMMUNOSUPPRESSION REGIMEN

PT #	*Cyclosporine (mg/day)*	*Azathioprine (mg/day)*	*Prednisone (mg/day)*	*Cyclosporine level(ria)*
1	300	150	15	84
2	300	150	20	85
3	350	150	20	132
4	450	125	17.5	108
5	400	25	25	112
6	250	150	25	126
7	300	150	20	85
8	800	150	25	198
9	400	125	20	135
10	400	150	25	204

Table 3
POST-OPERATIVE COMPLICATIONS

PT #	*Months Post TX*	*Rejection Episodes*	*Infection*	*Renal*	*Highest Creatinine*	*Current Creatinine*
1	13	1 Moderate 2 Mild	0	+	5.5(2)	1.3
2	10	1 Moderate 3 Mild	0	+	2.2(2)	1.6
3	9	1 Moderate 1 Mild	Bacterial Pneumonia	+	2.3(2)	1.6
4	7	0	0	–	1.6(2)	0.8
5	7	2 Moderate 1 Mild	Enterococcus Sepsis CMV	+	3.5(4)	1.3
6	6	0	0	+	2.9(2)	1.6
7	4	0	0	+	3.2(4)	1.6
8	4	1 Moderate 1 Mild	0	–	1.5(1)	1.5
9	3	0	0	–	1.2(3)	0.9
10	1	1 Mild	0	+	2.2(3)	1.3

Renal dysfunction was transient and required hemodialysis support in only one patient (#1), CMV = cytomegalovirus infection.

The post-discharge management of the transplant patient and the frequent adjustment of the triple immunosuppression regimen is coordinated thru the Hartford Transplantation Service. Out-patient follow-up, prospective data acquisition and organized record keeping are thus centralized to allow the art and the science of transplantation to grow in a controlled and methodic fashion.

Results

All ten patients undergoing heart transplantation at this institution during the past year are alive and well. This has occurred in the setting of national survival statistics which are improving annually. However, the most gratifying achievement of transplantation has been the improvement in life style and ability to return to full and gainful employment.[17] The first eight patients undergoing transplantation have all returned to work, almost all in the same or similar capacity to that preceeding their disability.

All patients undergo elective exercise stress testing three to six months following surgery to establish a functional ischemic baseline. This symptom limited test utilizes the standard protocol of Doan and Bruce with the only limitation being that of the denervated heart. The absence of pain fibers in the heart and the inability to achieve predicted maximal heart rate are both secondary to denervation and therefore preclude using this modality for long term follow-up regarding atherosclerosis. Nevertheless, all patients to date have exercised to fatigue with post-operative N.Y.H.A. Class I functional status.

Finally, all patients undergo elective, invasive evaluation at approximately one year post-transplantation.[18] Complete right and left heart cardiac catheterization is performed to obtain an accurate and reproducable baseline regarding the physiology, anatomy and hemodynamics of the transplanted donor organ. Three such evaluations have been performed to date on the first three patients operated upon and all were totally within normal limits.

Discussion

The art and science of orthotopic heart transplantation have evolved dramatically since the first operation as recorded in 1905 by Carrel and Guthrie in the American Journal of Medicine.[19] Nevertheless, much remains to be learned about the difficult questions relating to the fragile balance of infection and rejection as they relate to immunosuppression. Our favorable experience with triple immunosuppression utilizing cyclosporine, azathioprine and prednisone gives additional support to those who feel that balanced and diverse immunosuppression may be most optimal at the present time. It can reasonably be anticipated that we will continue to see increased survival and concomitant decreased morbidity along with lower costs secondary to reduced length of hospitalization. There will also be an increasing shortage of potential organ donors relative to the number of potential recipients.

In summary, the survival statistics and functional recovery of the patients transplanted confirm that cardiac transplantation has truly become established as an important therapy for selected patients with terminal cardiac disease. It is hoped that in the coming years orthotopic cardiac transplantation will continue to grow in Connecticut and worldwide in a controlled and responsible fashion as a therapeutic option for selected patients with end-stage heart disease not amenable to convential medical or surgical treatment.

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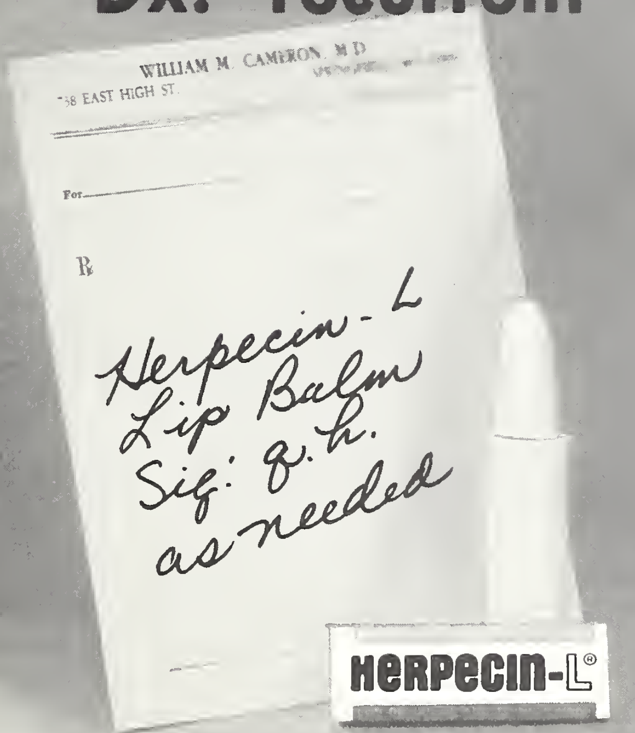
Dx: recurrent herpes labialis



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Clinically Relevant Factors in Transplantation Immunology

(First of Two Parts)

LAURINE M. BOW, M.S. AND ROBERT T. SCHWEIZER, M.D.

ABSTRACT—The immune defense mechanism against transplanted foreign tissues is formidable. The successful engraftment of an organ from another individual has therefore been a unique achievement of modern medicine. It has resulted from a combination of the use of medications which suppress the immune response, awareness of the antigenic disparity between individuals and methods to measure these differences, and the ability to alter the immune response of the host as well as the antigenicity of the donor organ. Important future advances in this field will very likely occur in these latter two approaches.

Overview of Part One

The science underlying the observed clinical aspects of organ transplantation at first appears enormously complex and beyond comprehension by the average physician or scientist. There is no denying that there is an ever increasing amount of detailed information in this field of immunology, but it is important because it provides an explanation for clinical events and thereby forms a basis for therapy.

An understanding of the immunology of organ transplantation first requires a few definitions. The transplantation of a tissue or organ from one individual to another within the same species is called an "allograft"; an older terminology was "homograft". Transplantation of an organ within the same individual, for example taking a kidney out, performing bench surgery on it and then placing into the pelvis, is an "autograft". Transplantation of an organ between different species is a "heterograft", or "xenograft." The "allograft rejection" process is an immune response by the recipient directed at an allograft.

The surgical history of organ transplantation began in the early 1900's when Alexis Carrel performed successful kidney transplants in animals. One of his kidney autografts survived several years. The allografts all rapidly failed because there were no drugs to suppress the rejection reaction. Carrel noted the cellular infiltration in those grafts and concluded that the lymphoid system probably had a major role in the destruction of the allografts. In the 1940's, Medawar showed that the cellular infiltration of the graft which resulted in its destruction was an immunologic event, not unlike reaction to a TB skin test. It was not until the early 1960's that drugs were discovered that could prevent organ transplant rejection. Successful organ transplantation between unrelated individuals was then possible.

In dissecting apart the immune response to a transplanted organ, an enormous amount of information has been obtained in the past few years. For example, lymphocytes are subdivided into two major types, T and B cells. T cells develop under the influence of the Thymus, and are involved with the cellular destruction of an organ transplant and other important defense functions. These cells are further subdivided into those which aid the immune response, "helper" cells, or those that will slow down or even prevent the rejection process, "suppressor" cells. Helper cells stimulate large numbers and types of cells such as cytotoxic cells, which are specifically committed to destroy the graft. Additional specialized types of lymphoid cells, such as macrophages, play a critical role in the recognition of foreign antigen, processing it and correctly presenting this antigen to T cells, thus triggering the immune response against the foreign antigen or organ transplant.

The B cells, or cells which are derived from the Bone marrow (or an analog in the chicken known as the Bursa fabricius), are cells which are primarily involved with the development of antibody. B cells differentiate into plasma cells which make antibody. Antibody is involved in the destruction of organ transplants, but is usually a serious

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problem only in patients sensitized against antigens of the donor *prior* to the transplant. This could occur through blood transfusions or pregnancy.

Antigens on the surface of cells of an organ transplant trigger the rejection process. These antigens are different from one individual to another, are very dense on the surface of lymphocytes, and thus permit determination of different types of antigens by testing of a blood sample. This antigen system is called the major histocompatibility antigen system (MHC), or human lymphocyte associated antigen (HLA). These antigens are very similar to the red cell antigens in their type of classification, but they are far more numerous, and they also have very important immunologic roles. For example, they are important in determining the difference between "self" and "non-self", i.e., between the cells which are circulating within us and obviously belong within us, versus the transplanted cell, or a cell no longer adhering to our normal protein synthetic functions. Such an aberrant cell might be a tumor mutant, which could be developing into a cancer. Thus, the HLA antigens serve an important role in other areas beside organ transplantation.

In the case of transplantation, the HLA antigens are responsible for triggering the cellular process that results in the destruction of the organ transplant. Matching for these antigens will reduce the antigenic differences between a donor and recipient, and can increase success of organ transplantation. The HLA antigens are concentrated in certain cells within an organ transplant, a feature which is of some clinical importance.

PART ONE

The recent dramatic advances in organ transplantation have been possible primarily because of improved methods to control or prevent the rejection process. This report will review the fundamental immunology of organ transplantation.

The first extensive series of organ transplants was performed in dogs and cats by Alexis Carrel in the early 1900's. [1] By comparing the success rates of autografted and allografted kidney transplants in these animals, it was apparent that in an allograft situation, the host was somehow responding to the presence of foreign tissue and damaging it to such an extent that the organ was no longer functional. In the absence of technical complications, these kidneys would produce urine postoperatively for a brief period only, whereas autografted kidneys would continue functioning.

This rejection of donor tissue was seen in other allograft systems as well, and the predictability of its occurrence diminished interest in organ transplantation for about ten years. In 1914 J.B. Murphy, a colleague of Carrel, discovered that radiation or benzol treatment would prolong the survival of tumor allografts in rats. From this data Carrel extrapolated these findings to the field of organ transplantation, and made the following statement at a meeting of the International Surgical Association:[1]

"It is too soon to draw any definite conclusions from these experiments. Nevertheless, it is certain that a very important point has been acquired with Dr. Murphy's discovery that the power of the organism to eliminate foreign tissue was due to organs such as the spleen or bone marrow, and that when the action of these organs is less active a foreign tissue can develop rapidly after it has been grafted."

"It is not possible to foresee whether or not the present experiments of Dr. Murphy will lead directly to the practical solution of the problem in which we are interested."

"The surgical side of the transplantation of organs is now completed, as we are now able to perform transplantations of organs with perfect ease and with excellent results from an anatomical standpoint. But as yet these methods cannot be applied to human surgery, for the reason that homoplastic transplantations are almost always unsuccessful from the standpoint of the functioning of the organs. All our efforts must now be directed toward the biological methods which will prevent the reaction of the organism against foreign tissue and allow the adapting of homoplastic grafts to their hosts."

Mechanisms of Immune Response

It has been 70 years since these conclusions were derived. Though the efforts to combat the problem of allograft recognition and destruction have been enormous, resulting in marked improvements in graft survival, the problem of allograft recognition and destruction by the host remains. The basic mechanisms by which a host recognizes foreign tissue can best be understood by first describing the way in which the host responds to an antigen, as shown in Figure 1.

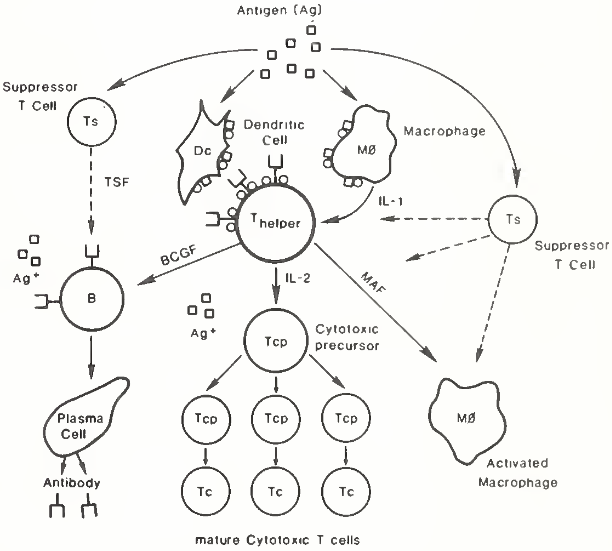

Figure 1

Activation of the immune system by antigen. Antigen (□) is first recognized and processed by dendritic cells and macrophages, which will consequently present this foreign material to T-helper cells. Antigen specific T-helper cells are stimulated by the antigen (□) and self-MHC molecules (o) on macrophages, and initiate cascade of events (see text).

Foreign antigen entering the host is first recognized by dendritic or macrophage cells which identify, process, and present it to regulatory T cells bearing specific receptors for that antigen. At the same time that macrophages present antigen, they also secrete a cytokine, interleukin 1 (IL-1), which activates a subgroup of T cells, called T helper cells which synthesize and release another regulatory molecule, interleukin 2 (IL-2). This molecule acts as a stimulant (mitogen) for cytotoxic precursor T cells which have been stimulated with specific antigen. Interleukin 2 causes these cells to undergo blastogenesis and develop into mature cytotoxic (killer) T cells.

T helper cells also augment the B cell response to produce antibody by secreting additional factors which cause antigen specific B cells to become activated and differentiate into plasma cells. The plasma cells then produce large amounts of a specific antibody.

In a general sense, it is apparent that the activation of the immune system network occurs when *two* signals are received by the immune responding cells: (1) a specific (antigenic) signal; and (2), a mitogenic (lymphokine) signal, which causes only those select cells specific for the antigen to proliferate. In this manner, the cells required to combat a foreign element are rapidly propagated. When that element is withdrawn, their propagation is halted abruptly.

Antigen can also be presented to regulatory T cells in such a manner as to activate another population of T cells, called suppressor cells. These cells diminish the immune response of the host to that antigen by producing suppressor "factors", both antigen specific and nonspecific in nature.

Another regulatory mechanism involving antibody production by B cells is the anti-idiotype network theory, first postulated by Jerne.[2] This theory is based on the observations that antibodies specific for a particular antigen possess unique determinants (cell surface antigenic molecules) which are in turn immunogenic to the host. These determinants are called idiotypes, and the host responds to these by producing antibodies against the idiotype. These anti-idiotypic antibodies have been postulated to regulate antibody production since their development corresponds to a decrease in specific antibody titers.

If we replace foreign antigen with an allografted organ in the above scheme, one can easily identify different pathways which could be interfered with to diminish the host's immune response to that organ as shown in Figure 2. Two major areas which have received much attention are: 1) decreasing the antigenicity or "foreignness" of the graft; and/or 2), decreasing the host's ability to respond to the transplanted graft. Currently in clinical transplantation, an attempt is made to affect both of those areas in order to prolong graft survival. The antigens which are recognized on the allograft are called major histocompatibility complex (MHC) antigens. The normal function of these antigens will first be discussed, followed by the role they play in organ transplantation.

Major Histocompatibility Antigens

Cell surface recognition systems capable of identifying and destroying non-self antigens have been found in organisms as primitive as sponges. If two genetically identical sponges are lined next to each other, they will fuse to form a single organism. If dissimilar, a reaction ensues which leads to tissue destruction at the boundary between the two. This reaction is presumably triggered by the recognition of non-self structures on the cell membrane. These molecules display an enormous number of differences (polymorphism), between individual sponges, which is one of the striking characteristics of self/non-self recognition systems.

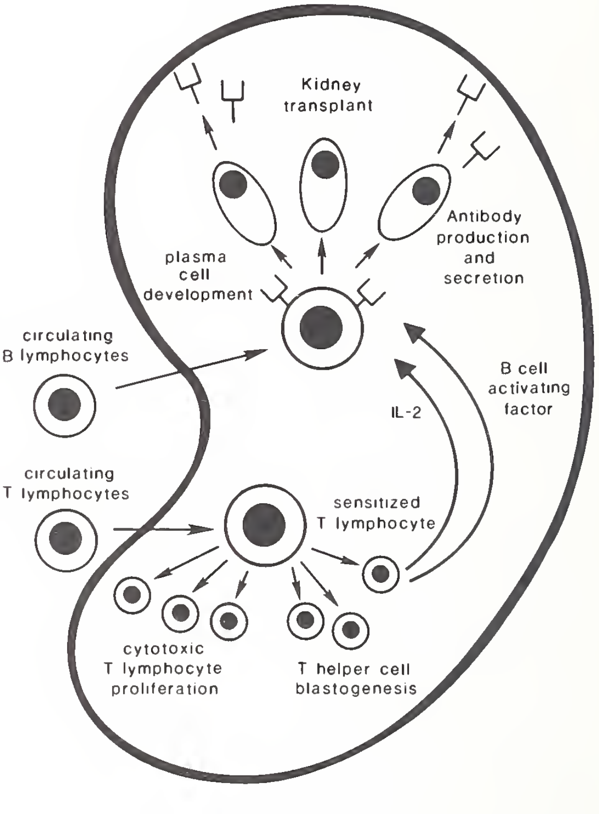
Kidney transplant
Antibody production and secretion
plasma cell development
circulating B lymphocytes
B cell activating factor
IL-2
circulating T lymphocytes
sensitized T lymphocyte
cytotoxic T lymphocyte proliferation
T helper cell blastogenesis

Figure 2

Simplified diagram of the activation of the immune system by an allogeneic kidney transplant. Most of this activity actually occurs in reticulo-endothelial tissue, (e.g. spleen and lymph nodes).

Lymphocyte Interactions Involving the MHC

A primary function of the immune system is to recognize foreign material. Therefore, it must discriminate between self and non-self. This system is controlled by having two signals, an identity signal and a regulatory component. The identity signal is a set of molecules found on all nucleated cells. In man, these are called the Class I antigens of the major histocompatability complex (MHC). Regulatory molecules are not present on all cells. They are primarily on cells which function as part of the immune system. A central feature of the immune response is genetic restriction, which simply means that "like" cells can interact and "unlike" cells do not. This implies that specific recognition occurs during cell-cell communication. The MHC antigens function in this specific recognition mechanism.

Evidence that the MHC products serve as the elements involved in the genetic restriction phenomenon was first given by Rosenthal and Shevach in 1973.[3] They demonstrated that T cells could only become activated when macrophages involved in presenting an antigen shared the same histocompatibility antigens as the T cells. They analyzed the immune response of two strains of guinea pigs, strain 2 and 13. These two strains of guinea pigs had different Class II (Ia) antigens on their macrophages. The experiments showed that macrophages of one strain could only activate T cells from animals of the same strain. Macrophages from strain 2 could not activate T cells of strain 13 because of the Class II antigen difference between those strains. The immune response was therefore "genetically restricted".

Other experiments using those same two strains of guinea pigs demonstrated another important feature of Class II histocompatible antigens. It was observed that strain 2 guinea pigs could respond to the antigen, L-glutamic acid-L-lysine (GL), while strain 13 animals could not respond to GL. This difference in response was found to be due to a unique feature of some Class II antigens, but not of others (e.g., those in strain 13 guinea pigs would not permit an immune response to GL).

The involvement of the thymus gland in controlling specific immune responses was investigated by Klein.[4] He first removed the native thymus glands of mice, and then exposed the animals to gamma irradiation to destroy the remaining peripheral lymphocytes. Half of the mice were reconstituted with thymus tissue from mice which normally exhibit an immune response to a specific antigen (responders), and the other half received thymus tissue from nonresponder animals, that is, those which were unable to elicit an immune response to the particular antigen. The animals were then challenged with that antigen. Those receiving the responder thymus responded to the antigenic stimulation, and those that received the nonresponder thymus did not respond. Therefore, it appeared that the thymus was responsible for the response, and that the Ia immune response determinant on the macrophage was not the only element involved in the regulation of an immune response.

The way in which the thymus controls the immune response to a particular antigen has been postulated by the "determinant selection theory". According to this theory, the reason why animals do not respond to certain antigens is because the clones of T cells specific for those antigens are somehow deleted during T cell maturation. Consequently, "holes" develop in the T cell repertoire responsible for recognizing antigen when presented by autologous macrophages. A corollary to this theory is that there is also deletion or suppression of anti-self reactivity in the thymus. In other words, the thymus will not allow development of T cells which would normally respond against the MHC molecules expressed by a person's own cells. Concurrently, the thymus positively selects for T cells which recognize self MHC molecules + "X", i.e., Ia determinant + foreign antigen.

A puzzling question in transplantation immunology is why the immune response against transplanted tissue is so vigorous. One possible reason is that MHC determinants expressed on transplanted tissue may resemble self MHC determinants combined with foreign antigens that the host has previously been exposed to. If we refer back to Figure 1, it will be noted that the macrophages of an individual, which have Ia determinants on their surface, are at the same time presenting the foreign antigen to T helper cells. These T cells recognize the "combination" of foreign antigen and self MHC determinants on the macrophages. Perhaps MHC foreign antigens (alloantigens) structurally appear as self Ia + antigen, and trigger the T cells to generate an immune response against them. The host's immune repertoire may vigorously attack cells bearing these alloantigens simply because they look, for example, like a virally infected autologous cell which normally elicits a vigorous attack.

MHC Antigens in Transplantation

Although the exact mechanism by which host T cells are programmed to recognize donor (allogeneic) tissue is unclear, it is apparent that the host does indeed respond to the presence of foreign histocompatibility antigens expressed by the transplanted tissue. The ensuing immune response which these antigens evoke will ultimately lead to total tissue destruction. As has been mentioned previously, one way of diminishing the host's immune response to foreign tissue is to decrease the antigenicity of the graft. This might be accomplished by simply matching donors and recipients for MHC antigens, so that the degree of difference between the two will be minimized. This has been shown to be most effective in living related kidney transplantation where the donor and recipient are siblings. In cases where there is a complete match for MHC antigens, graft survival rates approach 95%. Unfortunately, the correlation between tissue match and graft survival is much less striking in cadaveric kidney transplantation. Possible reasons for this descrepancy will be explained later.

A schematic representation of the major histocompatibility complex, which is located on human chromosome 6, is depicted in Figure 3. Of the many subloci so far characterized, four have been shown to be important in affecting transplant survival: these are A, B, DR, and D. The A and B subloci encode for the classical HLA antigens, which are now called Class I MHC antigens. These antigens are most easily tested for by reacting cells expressing these molecules with antisera containing antibodies for the different HLA antigens in a cytotoxicity assay. If the cells express a certain antigen, antibody contained in a specific serum will bind to the cell, and subsequent addition of complement will lyse the cell. This lysis is easily identified by dye exclusion microscopically. Antigens coded by the DR sublocus, which are Class II molecules, are also detected in this manner. However, the DR antigens are not expressed on all lymphocytes, the cell routinely used for testing purposes. Only B lymphocytes, which constitute approximately 10% of the peripheral blood lymphocyte population, have DR antigens. Therefore the cell suspension used for typing purposes must be enriched for this particular cell type.

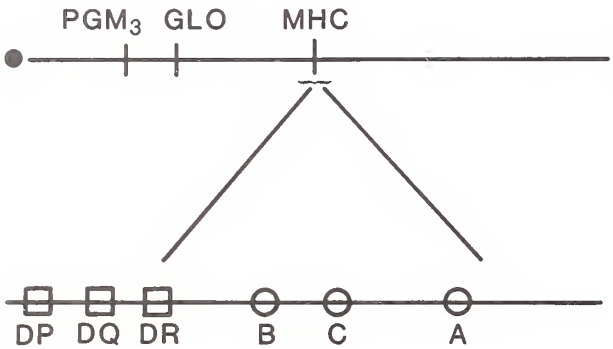

Figure 3

Schematic diagram of the human major histocompatibility complex on the short arm of chromosome 6. The MHC is expanded in the lower portion with the class I loci represented by circles, and the class II by squares.

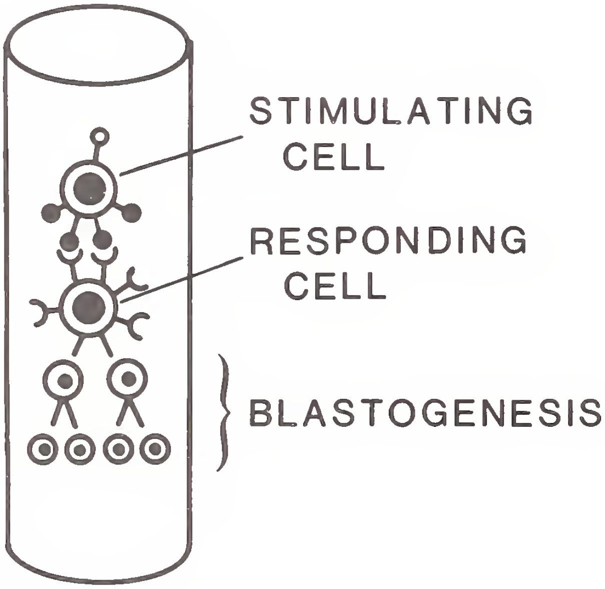

Figure 4

Diagram of the mixed lymphocyte reaction. Stimulating cells are inactivated by irradiation and consequently cannot undergo blastogenesis. Responding cells recognize foreign HLA-D antigens on the stimulators and are activated to proliferate. As the cells replicate, ^{3}H thymidine is incorporated into their DNA; and the amount is measured by scintillation counting.

Antigens of the D sublocus, which are also Class II molecules, are defined by a mixed lymphocyte reactivity (MLR) assay (Figure 4). When two cell populations, each expressing different D antigens are cultured together, the lymphocytes will respond to the presence of these foreign antigens by undergoing blastogenesis.

As shown in Table 1, the major histocompatibility complex is extremely polymorphic. New antigens are continuously being defined as better reagents become available. It is obvious that it is no easy task to obtain complete ("perfect") matches for the antigens involved when one is attempting to match cadaveric kidney donors to recipients. In living related sibling pairs, as the antigens are inherited from each parent, the possibility of obtaining an identical match is 25%, as can be seen in Figure 5. Even when complete matches are obtained between cadaver kidney donors and recipients, graft survival rates are not improved to the same degree as those in living related transplants. Although the exact reason for this discrepancy is not known, it has been postulated that differences in minor histocompatibility loci between donor and recipient adversely affect graft survival.

Table 1

WHO Recognized HLA Specificities from the IX Histocompatibility Workshop

A	B	C	D	DR	DQ	DP
A1	B5	Cw1	Dw1	DR1	DQw1	DPw1
A2	B7	Cw2	Dw2	DR2	DQw2	DPw2
A3	B8	Cw3	Dw3	DR3	DQw3	DPw3
A9	B12	Cw4	Dw4	DR4		DPw4
A10	B13	Cw5	Dw5	DR5		DPw5
A11	B14	Cw6	Dw6	DRw6		DPw6
Aw19	B15	Cw7	Dw7	DR7		
A23(9)	B16	Cw8	Dw8	DRw8		
A24(9)	B17		Dw9	DRw9		
A25(10)	B18		Dw10	DRw10		
A26(10)	B21		Dw11(w7)	DRw11(5)		
A28	Bw22		Dw12	DRw12(5)		
A29(w19)	B27		Dw13	DRw13(w6)		
A30(w19)	B35		Dw14	DRw14(w6)		
A31(w19)	B37		Dw15			
A32(w19)	B38(16)		Dw16	DRw52		
Aw33(w19)	B39(16)		Dw17(w7)	DRw53		
Aw34(10)	B40		Dw18(w6)			
Aw36	Bw41		Dw19(w6)			
Aw43	Bw42					
Aw66(10)	B44(12)					
Aw68(28)	B45(12)					
Aw69(28)	Bw46					
	Bw47					
	Bw48					
	B49(21)					
	Bw50(21)					
	B51(5)					
	Bw52(5)					
	Bw53					
	Bw54(w22)					
	Bw55(w22)					
	Bw56(w22)					
	Bw57(17)					
	Bw58(17)					
	Bw59					
	Bw60(40)					
	Bw61(40)					
	Bw62(15)					
	Bw63(15)					
	Bw64(14)					
	Bw65(14)					
	Bw67					
	Bw70					
	Bw71(w70)					
	Bw72(w70)					
	Bw73					
	Bw4					
	Bw6					

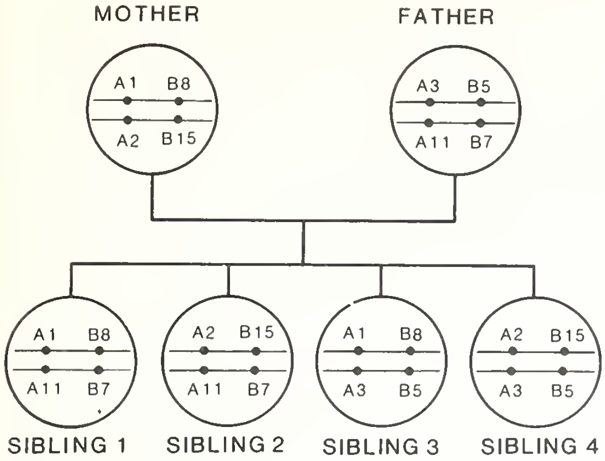

Figure 5

The inheritance and co-dominant expression of haplotypes in a family. Two siblings inheriting the same haplotypes would be identical to each other.

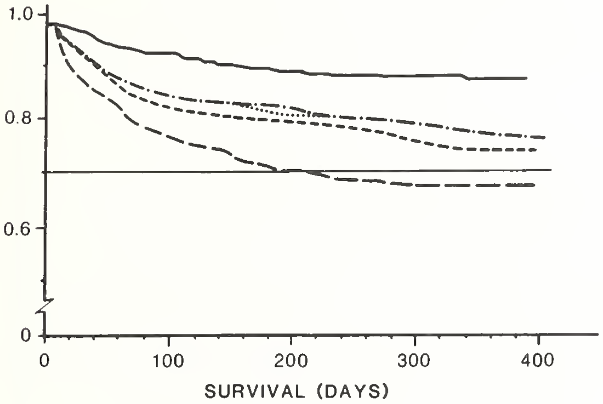

Figure 6

Analysis of HLA-B and DR mismatches in first cadaver kidney transplants receiving cyclosporine. Fraction of grafts surviving (vertical axis) are depicted for those patients receiving 0 mismatch (———), 1 mismatch (• • • •), 2 mismatch (—•—•—•—), 3 mismatches (– – – –), and 4 mismatches (—— ——) grafts. Over 3,000 patients were analyzed.

The question of whether or not matching of histocompatibility antigens has a significant effect on graft survival in cadaver transplants has been an area of controversy. In recent years large scale studies consisting of pooled data from many transplant centers have provided much information concerning multiple parameters affecting graft survival, including histocompatibility. Results from the Collaborative Transplant Study,[5] which is currently gleaning data from transplant centers internationally, is shown in Figure 6. This graph depicts the percentage of graft survival in comparison to the degree of histocompatibility between donor and recipient. As can be seen, there is a definite improvement in transplant survival as the number of mismatched antigens is minimized, even when the powerful immunosuppressant cyclosporine is used for immunosuppressive therapy.

Passenger Leukocytes

It has been demonstrated since the early 1970's that a certain cell population residing in transplanted rat kidneys, originally called "passenger leukocytes", were the major cells involved in evoking the immune response of the host against that tissue.[6,7,8] This conclusion was derived from experiments where removal of these leukocytes by pretreatment of the graft with cyclophosphamide resulted in significant prolongation of transplant survival. It is now known that these cells are dendritic cells, and the normal function of these cells is to present antigen to immunocompetent cells, as was earlier described in Figure 1.

Dendritic cells express an extremely high concentration of Class II molecules, and this characteristic has been implicated as being responsible for their ability to elicit a strong immune response from allogeneic immune responding cells. When transplanted tissue is treated in a way to injure the DR antigens, the immune response of the host against the graft is greatly diminished. This has been accomplished with pretreatment of transplanted rat tissue with monoclonal antibodies directed against Class II antigens,[9] or exposure to ultraviolet irradiation which damages these cells in a manner similar to pretreatment with cyclophosphamide.[10] This effect is especially pronounced in pancreatic islet cell transplantation in rats, where removal of dendritic cells with antibody against Class II antigens destroys the dendritic cells enmeshed in the islet. These islet cells will survive indefinitely after allotransplantation, resulting in a cure of the rat which was previously rendered diabetic by chemical destruction of islet cells.

An obvious conclusion from these studies is that an effective way to prolong graft survival in humans is to remove dendritic cells, thereby removing antigenicity. Indeed, many attempts have been made to remove these cells to achieve this goal. For example, investigators have tried to kill dendritic cells in transplanted kidneys by perfusing the organ with cyclophosphamide prior to transplantation. These manipulations have failed, and the most likely reason for this is the fact that, unlike the rat, the vascular endothelium of human tissue expresses Class II molecules.[11] Therefore, even if all dendritic cells are removed, the vascular tissue still contains enough of these molecules to sensitize the host. Although this difficulty exists in large vascularized organ transplants, removal of dendritic cells in pancreatic islet cell transplantation is still a promising idea as an aid in avoiding allograft rejection.

We have thus far discussed some of the many parameters involved in generating an immune response, and in particular, those areas which are especially involved in organ transplantation. In the second part of this article, to appear in the next issue of *Connecticut Medicine*, we will discuss how the immune response of a recipient can be manipulated to permit organ transplant survival.

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Cocaine, Myocardial Infarction and Arrhythmias—A Review

MARTIN DUKE, M.D.

In the last few years, an increasing number of patients have been described in whom a relationship has been implicated or suspected between cocaine use and various manifestations of heart disease. In view of the expanding recreational use of cocaine, especially in the young, usually healthy and frequently athletic individual, it seems timely to consolidate and review the clinical characteristics of these patients.

Cocaine is known to produce a sympathetically mediated tachycardia and vasoconstriction.[1] Both the intranasal and the intravenous routes of administration may result in this pressor response and acceleration of heart rate.[2,3] In addition, a large intravenous dose of cocaine can have a direct toxic effect upon the heart itself.[4]

Myocardial Infarction and Cocaine

A search of the current literature identified thirteen patients[5-10] in whom there was felt to have been an association between cocaine use and an acute myocardial infarction. (See Table for specific cases) This group consisted of 12 males and one female ranging in ages from 21 to 44 years. A positive history for cigarette smoking was present in 10 of the 12 patients in whom this information was available, with one patient having hypertension and diabetes.[6] An electrocardiogram showed a new or acute myocardial infarction in all 13 patients with appropriate enzymatic documentation. Coronary angiographic studies were performed in 10 patients, with the period of time between the infarction and the test as noted in the Table. Occlusive coronary artery disease was demonstrated in 7 of these patients, with significant disease being limited to a single major coronary artery in all but one individual.[9] In the remaining three patients, the angiographic studies were normal 1 week, 2 weeks and 18 months respectively after the occurrence of the infarct.[7,8,10]

The route of cocaine administration was known in 12 patients—inhalation or intranasal ("snorting") in 8, intravenous in 3, and both pathways in one. All were chronic users, with 5 also reporting additional use of alcohol and/or heroin.[5,10] The duration of time from initially starting to inhale cocaine to the onset of the infarction varied in four patients from 2-3 hours to 5 hours.[7-9] The amount of cocaine used in two of these patients was 0.25 g and 1.5 g respectively.[7,8] One patient with triple vessel disease had coronary artery bypass surgery performed six weeks following the infarction.[9]

A recent abstract by Isner and his associates[11] briefly summarized the cardiac consequences of non-intravenous cocaine abuse in seven young adults in whom there occurred a myocardial infarction (4), ventricular fibrillation

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Table

COCAINE USE AND ACUTE MYOCARDIAL INFARCTION – A CLINICAL PROFILE OF 13 PATIENTS

Reference Number	*Age (yrs)*	*Sex*	*Cigarettes*	*Cocaine*		*ECG Site of Infarction*	*Coronary Angiogram ( )**
				Inh	*IV*		
5	30	M	+	0	+	Ant	LAD occlusion; infarction at autopsy (4 days)
5	44	M	+	+	0	Inf	No
5	43	M	+	+	0	Inf	Right coronary occlusion (NS)
5	36	M	+	0	+	Ant	Circumflex 75% narrowed (2 months)
5	27	M	+	+	+	Ant, Inf	No
5	35	M	+	0	+	Ant	LAD 90% narrowed (2-3 weeks)
6	42	M	+	+	0	Inf	No
7	21	M	0	+	0	Inf	Normal; ventricular function normal (1 week)
8	28	F	0	+	0	Ant	Normal; ventricular function normal (2 weeks)
9	35	M	+	+	0	Ant	Triple vessel disease, ventricular dysfunction (6 weeks)
9	37	M	+	+	0	Ant	LAD disease; ventricular dysfunction (NS)
9	38	M	+	NS	NS	Ant	LAD disease; ventricular dysfunction (NS)
10	30	M	NS	+	0	Ant	Normal; ventricular dysfunction (18 months)

( )* indicates time from infarction to coronary angiogram; + = Yes; 0 = No; NS = not stated; Inh = inhalation or intranasal; IV = intravenous; Ant = anterior; Inf = inferior; LAD = left anterior descending coronary artery

(1), myocarditis (1), and sudden death (1). Coronary angiographic studies were normal in 3 patients, two of whom had sustained a myocardial infarction. As more complete information was not available in these patients, they are not included in the Table. However, their ages and coronary artery studies appeared to have been very similar to others reviewed in this report.

Acute fatal pulmonary edema occurred in a 36 year old man following intravenously administered freebase cocaine.[12] No additional information regarding the heart was available.

Arrhythmias and Cocaine

Benchimol and his associates[13] described a 37 year old man who complained of palpitations after receiving 140 mg of cocaine intravenously over a 2 day period. An accelerated ventricular rhythm was documented. A second patient developed asystole and ventricular fibrillation following intravenous cocaine administration.[14] The autopsy examination disclosed cerebral edema. In a third patient,[15] supraventricular tachycardia and myocardial ischemia were documented following the intranasal use of a large amount of cocaine and the ingestion of alcohol.

And finally, normal electrophysiologic testing, including programmed ventricular stimulation, and a normal coronary angiogram and negative ergonovine response, were demonstrated by Isner and associates[11] in a 37 year old man with ventricular fibrillation following non-intravenous cocaine use.

Discussion

Blood pressure elevation and tachycardia such as that seen with cocaine administration may increase the double product and myocardial oxygen demand. If this were to occur either in the presence of fixed coronary artery obstruction or in the setting of coronary artery spasm, myocardial ischemia and/or myocardial infarction could result. In addition, cocaine interferes with the uptake of norepinephrine at the adrenergic nerve endings, thereby producing sensitization to catecholamines,[1] and raising the possibility that this mechanism may account for the development of arrhythmias or other manifestations of myocardial injury. A pathophysiologic process by which cocaine exposure itself may lead to coronary artery vasoconstriction, thrombosis, etc., remains to be shown.

When a cardiac event occurs in a young adult, particularly in the absence of risk factors such as hypertension or diabetes, it might be appropriate to consider the possibility of cocaine use as a precipitating factor. Whether the concomitant use of other drugs or cigarettes in these patients has any additional role is a matter of conjecture. The acute management of a myocardial infarction or arrhythmia following cocaine use would be similar to that indicated for any other patient, although an awareness of possible interactions of cocaine with other medications being used should be kept in mind. In the long term management of these patients, further use of cocaine should obviously be avoided. Beta-adrenergic blocking agents[16] or calcium channel blockers[17] have also been suggested for treating the cardiovascular effects of cocaine, although experience with these drugs is limited and difficult to evaluate.

The accumulated data discussed in this review indicates that 1) both the intranasal (inhalation) and intravenous routes of cocaine administration may be implicated in the precipitation of an acute myocardial infarction or an arrhythmia, confirming the observation that serious clinical events, including death, [18] are not limited to intravenous cocaine users, and that 2) these cardiac events may occur in young adult users of cocaine with both angiographically normal and abnormal coronary arteries.

Addendum:

Following acceptance of this article for publication, an additional report appeared describing recurrent myocardial infarctions in a young man, each event apparently related to intranasal cocaine abuse (Weiss RJ: Recurrent Myocardial Infarction Caused by Cocaine Abuse. Am Heart J 111:793, 1986).

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Progressive Pulmonary Infiltrates in a Man with Erythroleukemia

Morbidity and Mortality Conferences of the University of Connecticut Health Center

HENRY SCHNEIDERMAN, M.D., RICHARD A. GARIBALDI, M.D.
AND ROBERT BONA, M.D.

ABSTRACT— This conference discusses an elderly man with a myelodysplastic syndrome, who evolved an acute erythroleukemia. Rapidly progressive pulmonary infiltrates proved at autopsy to be due to fulminant invasive aspergillosis permeating the lungs; extrapulmonary metastatic infection produced other problems. Multiple correlations of clinical data with pathology are presented, including a novel ecthyma-like metastatic cutaneous lesion. The problem of nosocomial infections in the granulocytopenic patient in general, and infections with *Aspergillus* and JK bacilli in particular, are also addressed.

Series Editor's note: Morbidity and Mortality (M and M) Conferences differ in an important respect from Clinico-Pathologic Correlation Conferences (CPCs) such as those published weekly in the *New England Journal of Medicine*. In M and M conferences, pathologic information, including autopsy if available, is included in the data base. The discussions utilize the findings to expand upon points of diagnosis or management, or to glean insight about the entity in question. The issue of arriving at the diagnosis is not a central concern as it is in CPCs.

The following represents a heavily edited and expanded version of comments made in a Morbidity and Mortality Conference at the University of Connecticut Health Center, Farmington, CT.

Robert Bona, M.D.: A 68-year-old man was admitted to University of Connecticut Health Center to receive intensive therapy for acute erythroleukemia.

Fifteen months earlier, at another institution, mild macrocytic anemia was detected on a routine blood count. Eight months prior to admission, repeat studies showed a hemoglobin of 7.1 gm/dl; the mean corpuscular volume (MCV) was 119 cubic micra, the white blood count (WBC) 13,000 per cu. mm., and the platelet count 117,000 per cu. mm. Bone marrow aspirate and biopsy showed panhypercellularity without myelodysplasia. Restoration and maintenance of adequate erythroid function required the administration of 2 units of packed red blood cells monthly. Androgens and steroids were of no avail.

Four months prior to admission, pancytopenia had developed, with a hematocrit of 15%, WBC of 2000, and platelet count of 30,000. Intermittent platelet transfusions were added. By one month prior to admission, the peripheral blood smear contained 10% blast forms; repeat bone marrow aspirate and biopsy showed hypercellularity, pockets of blasts, and dysplastic changes in both myeloid and erythroid series. A diagnosis of myelodysplastic syndrome (preleukemia) was made.

Upon admission, the pulse rate was 100 beats per minute, the respirations 22 per minute, and the temperature 37 °C (98.6 °F). Examination of the skin was normal, as were the head, eyes, ears, nose and throat. No lymph nodes were palpably enlarged. The lungs revealed scattered wheezes only. The first and second heart sounds were normal. There was a mid-systolic ejection murmur at the tricuspid focus. No pericardial rub was present. Carotid pulses were slightly diminished. Both femoral arteries had bruits; foot pulses were absent. The jugular venous pressure was 7 cm of water. Liver and spleen were not enlarged. The ankles showed moderate, symmetric pitting edema, and venostatic discoloration. Neurologic examination was normal.

The urine was normal. Blood counts confirmed persistent pancytopenia. The peripheral smear showed

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Grant support: Dr. Schneiderman is a Teaching and Research Scholar of the American College of Physicians.

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anisocytosis, poikilocytosis, circulating nucleated red cells, and 30% blasts with morphologic features of erythroblasts, which stained with periodic acid-Schiff (PAS) reagent. Myelomonocytoid blasts were also seen.

Henry Schneiderman, M.D.: In the marrow aspirate and biopsy taken on admission, hypercellularity reflected a predominance of abnormal erythroid elements, with dyserythropoiesis. Blast cells and morphologically abnormal normoblasts abounded. The PAS stain showed intense cytoplasmic positivity in many abnormal cells, a finding highly characteristic of erythroleukemia. There was maturation arrest in the myeloid line. Megakaryocytes were decreased. Over 40% of marrow cells were blasts. Acute erythroleukemia, evolving from preleukemia, was diagnosed.

Dr. Bona: Chest radiograph showed cardiomegaly and prominent bronchovascular markings, without acute disease (Figure 1). ECG showed Q waves in leads V1 and V2, suggesting remote anteroseptal wall myocardial infarction, and nonspecific T wave flattening.

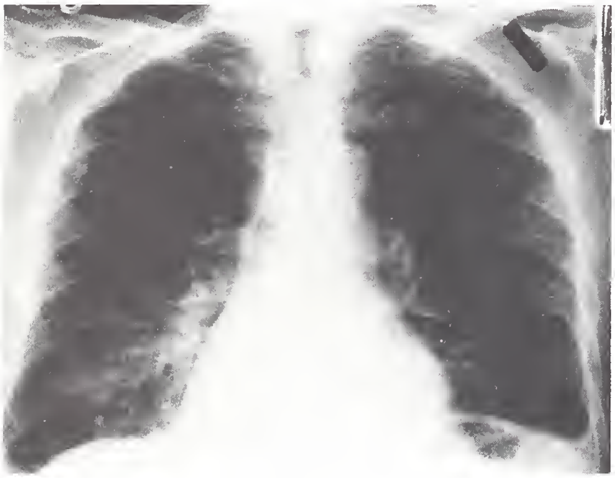

Figure 1
Chest radiograph on admission shows no parenchymal lung disease.

Therapy was begun with high-dose cytarabine (ARA-C), at 3 gm. per square meter body surface area, twice daily for six days. Anthracyclines were avoided because of the patient's age and cardiovascular disease.

Slight fevers developed upon initiation of antineoplastic therapy, without any evident cause. Five days into treatment, neutropenia appeared. With persistence of fever, and no clear source, broad-spectrum antibacterial coverage with gentamicin and ticarcillin was begun. Oral candidosis appeared and was managed topically. On day 13 of therapy, the patient complained of excessive fatigue, and was noted to appear acutely ill without localizing signs. That evening the fever rose to 38.6°C (101.5°F). New right middle and lower lobe pulmonary infiltrates appeared on radiographs, with a question of left lower lobe infiltration as well. There was mild hypoxemia, with an arterial blood pO2 of 59 torr on room air. After cultures were obtained, erythromycin was added for improved coverage of *Legionella*. Repeat bone marrow studies next day confirmed marked chemotherapy effect, with loss of both neoplastic and normal elements. The same day, because of persistent fever and progressive infiltrates, diagnostic bronchoscopy was performed. Thrombocytopenia precluded transbronchial biopsy, but brushings were obtained. No etiologic diagnosis was reached. Trimethoprim-sulfamethoxazole was added to cover for pneumocystosis. By that evening, respiratory dysfunction worsened, with increased radiographic "whiting-out." Transfer to the Intensive Care Unit, respiratory arrest, endotracheal intubation and mechanical ventilation followed in short order. Amphotericin B was added against the possibility of fungal pneumonia, and trimethoprim-sulfamethoxazole, erythromycin and gentamicin were continued.

Blood cultures from the onset of deterioration now grew a gram-positive species initially regarded as staphylococcal, but later identified as a corynebacterial "J-K" bacillus. Oxacillin was added for antistaphylococcal effect. This was later replaced with vancomycin in hopes of improving efficacy in case *Staph. epidermidis* were present, and to improve corynebacterial coverage.

Small erythematous papules developed over the anterior chest. Two evolved into an ecthyma gangrenosum-like lesion with erythematous margin and blackened center, suggesting subepithelial or deep dermal necrosis (Figure 2).

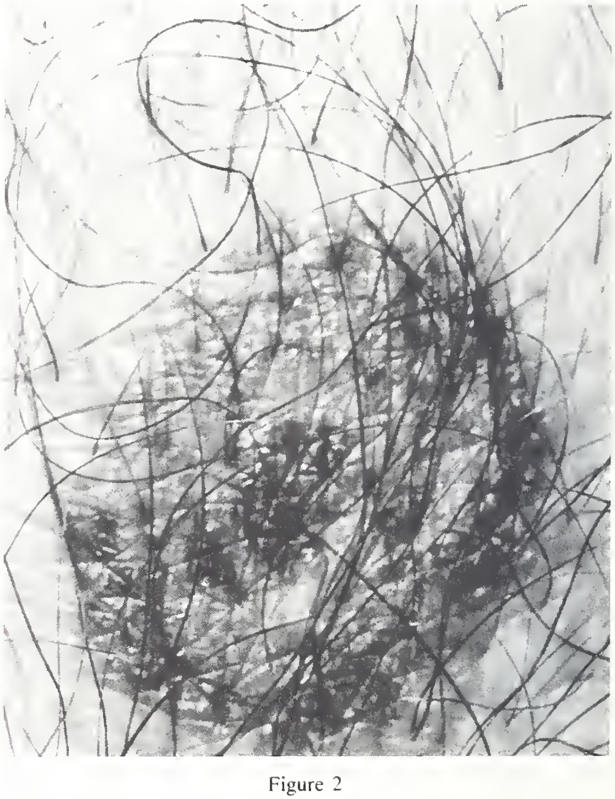

Figure 2
Cutaneous lesion near nipple is dark, flat and dermal.

Biopsy of one of these grew out J-K bacilli; no specimen was received for histopathology. Over the next 72 hours, deterioration was marked by need for increasing positive end-expiratory pressure for ventilation; progressive macronodular pulmonary infiltrates (Figure 3); supraventricular tachyarrhythmias, controlled with verapamil; pressor-dependent septic shock; and finally death, 20 days after the initiation of chemotherapy.

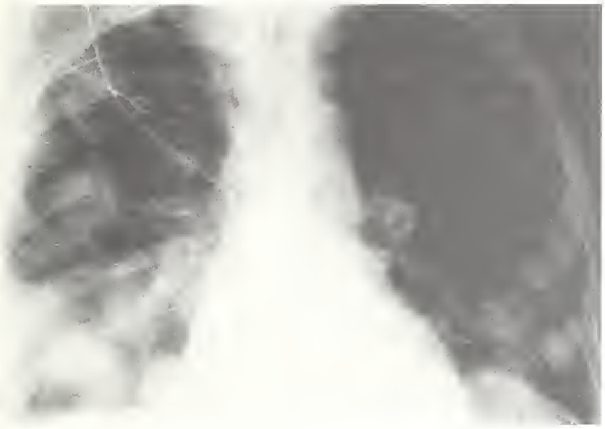

Figure 3
Chest radiograph taken late in hospital course shows multiple bilateral nodular pleuropulmonary densities.

Dr. Schneiderman: At external autopsy examination, a 1.3 cm dark lesion was seen just superolateral to the left nipple, having intact epithelium, some streaking, and a black center.

Internally, the parietal pericardium contained numerous nodules suggesting leukemic infiltrate or fungal colonies. They ranged up to 1.5 cm across, and from red and granular to brown, shaggy, and papillary (Figure 4).

The heart contained no vegetations. Myocardial fibrosis centered on the anterior wall of the left ventricle, corresponding to the loss of forces in the ECG. The epicardium was studded with petechiae (although there were no signs of disseminated intravascular coagulation). Since there had been no resuscitative attempts, a traumatic origin could not be invoked. Microinfarctions of varying ages were shown on histologic sections.

The lungs weighed 1500 gm each (top normal 350). Parasagittal sections showed bulging dry, intense red nodules up to 4 cm across that had darker erythematous rims (Figure 5). The nodules corresponded to the round radiographic densities (Figure 3). They were brighter red than ordinary infarcts, and many contained *in-situ* thrombi conforming to the shape of pulmonary arteries. Such thrombi lacked the irregularity, venous valve markings, or pleural propensity of conventional pulmonary emboli; and some were more tan-colored than emboli. Microscopy of lungs, pericardium, diaphragm, skin lesion, and a renal infarct, showed hemorrhage, infarction, and thrombi caused by pervasive aspergillosis, and a feeble inflammatory reaction. The fungi were seen in greater numbers on silver methenamine stain than on conventional hematoxylin and eosin. Aspergilli produced thrombosis and infarction by invading arteries and proliferating extensively. Free growth into and out of vessels was highly typical of aspergillosis. High power examination confirmed relatively wide (5 micra) hyphae, whose size and septations excluded the species that cause mucormycosis (phycomycosis). The hyphae did not bulge "sausage-fashion" near septa. They branched at forty-five-degree angles; yeast forms and chlamydospores were lacking (Figure 6). For all these reasons, *Candida* was excluded. Microscopy of the cutaneous lesion confirmed epithelial integrity over widespread, vasoinvasive dermal aspergillosis. The pericardial aspergillus lesions contained more fibrin, accounting for the difference in gross appearance.

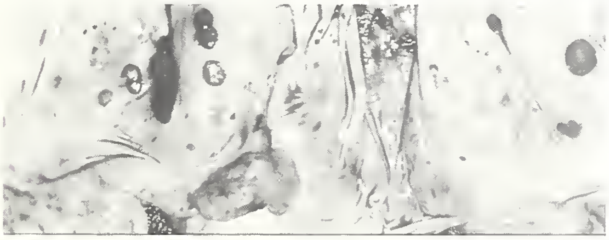

Figure 4
Parietal pericardium thickly studded with macroscopic aspergillus colonies and scant host response, chiefly fibrinous.

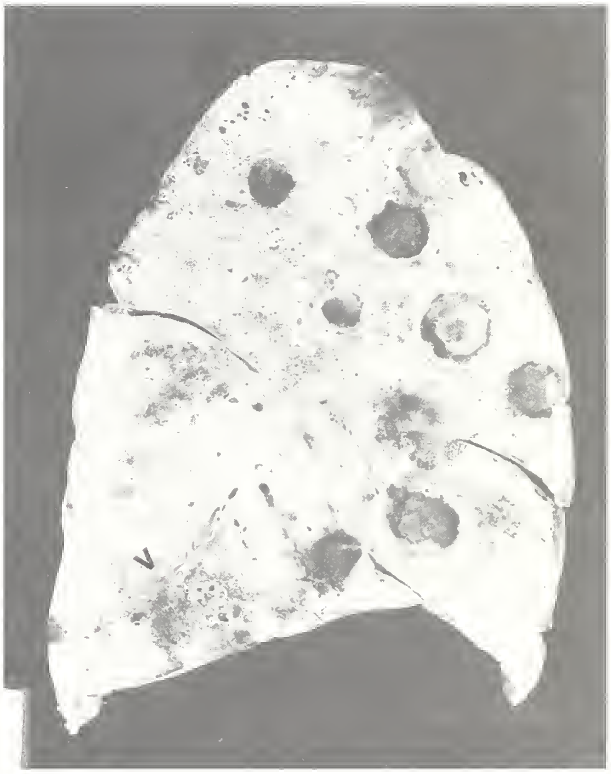

Figure 5
Parasagittal section of right lung shows trilobar involvement with aspergillosis, in both infarctional nodules and bronchopneumonic form. Arrowhead shows an aspergillus thrombus.

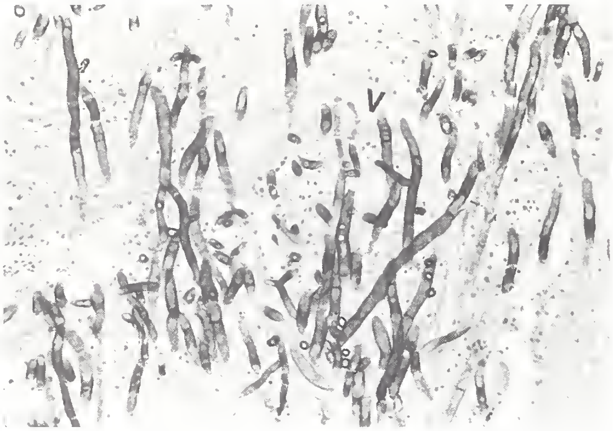

Figure 6
Histologic section demonstrates aspergilli invading and thrombosing pulmonary artery (arrowhead), and pervading lung parenchyma. Septate hyphae have 45-degree-angle branching. (Silver methenamine stain, original magnification 400X.)

The hypoplastic bone marrow, lymph nodes and spleen contained cells suggesting residual leukemia. Excess hemosiderin in liver and spleen reflected the multiplicity of transfusions.

Thus, the pulmonary pathology accorded closely with the clinical and radiographic findings, reflecting virtually unopposed tissue invasion by the pathogen, and the vaso-occlusive consequences of its tendency to enter blood vessels. The absence of pericardial signs, given the extent of involvement, may have reflected the difficulty of detecting them in a critically ill patient with noisy respiration. That the diaphragmatic lesions would be silent is predictable, as is the lack of specific findings from a small (septic) renal infarct. The cutaneous lesion, a variant of ecthyma, reflected the same process that was evident in the lungs. It resembled the secondary cutaneous lesions of systemic *Pseudomonas* infections, and the palatal lesions of mucormycosis: the causative species share a tendency to vascular invasion in the immunocompromised patient. Of note, this skin lesion has not been previously clearly distinguished in aspergillosis.[1-3] Skin lesions have been recognized as the site of origin, and portal of entry, of systemic aspergillosis.[4] Such lesions, however, are typically at sites of venoclysis boards, and invariably show breaching (ulceration) of the epidermis; they thus differ importantly from the secondary (metastatic) lesion in systemic, fungemic infection, described above.

Richard A. Garibaldi, M.D.: Granulocytopenic patients who receive empiric, broad-spectrum antibiotics are susceptible to many nosocomial pathogens. These include not only the well-recognized gram-negative rods, but also a variety of gram-positive bacteria and fungi. These opportunistic pathogens have in common their resistance to conventional antibiotic therapies. The present case provides a dramatic illustration of the infectious complications of granulocytopenia, one that is somewhat atypical in the rapidity of onset of nosocomial infections.

Anti-leukemic chemotherapy with an extremely high dose of cytarabine represented a relatively new chemotherapeutic approach. In this case, it caused marrow remission. Profound granulocytopenia occurred eight days after therapy was initiated, and persisted until death. It remains to be seen whether or not this type of chemotherapeutic approach with high-dose therapy will produce an increased incidence of opportunistic infections.

On the day chemotherapy was begun, a Hickman catheter was placed. It is noteworthy that a low-grade fever ensued on that day; the patient remained febrile over the next three weeks. Empiric antibiotic therapy with gentamicin and ticarcillin was initiated when the white blood cell count plummeted to less than 100 neutrophils per cubic mm. The course was relatively stable over the next six days, but then another febrile episode was associated with new bilateral pulmonary infiltrates. Blood cultures drawn that day grew a gram-positive organism after two days' incubation. This organism grew relatively slowly and its final identification and sensitivity test results were not available until one week later. Subsequently, the isolate was identified as a coryneform bacterium of the JK group.

This bacterial genus was identified as a cause of prosthetic valve endocarditis in the mid-1960s. More recently it has been noted to be an opportunistic pathogen in severely immunosuppressed patients. Identification of this organism as a cause of bacteremia is important because of its multiple antibiotic resistance. Generally, coryneform bacteria of the JK group are resistant to penicillin, ampicillin, oxacillin, erythromycin, clindamycin and cephalosporins. They are regularly sensitive only to vancomycin, and variably sensitive to rifampin and tetracyclines. Corynebacteria colonize less than 1% of normal persons outside the hospital setting. They are found in 13% of hospitalized, non-immunosuppressed patients and may colonize up to 40% of immunosuppressed hospitalized patients.[5] They colonize the rectal area, groin, axilla and upper airways of these patients. They can cause wound infections, bacteremia and endocarditis. They have been identified as significant pathogens in immunocompromised patients who are predisposed to infection by virtue of their profound granulocytopenia, long-term receipt of antimicrobics, and disruptions in skin defense systems, such as with intravenous catheters. The outcome of infection is related to the use of appropriate antibiotics, and to removal of potentially contaminated intravenous catheters that may be foci of infection. It is significant that JK coryneform bacteria were isolated not only from the bloodstream, but also from the papular skin lesions during the last days of life.

Recently, it has been reported that bacteremias in patients with Hickman or Broviac catheters can be successfully treated without removing the catheter.[6] Treatment can be successful even when the granulocytopenia is not reversed. Nonetheless, certain complications should prompt removal of the catheter. These include the demonstration of thrombus in the catheter, persistent bacteremia in blood cultures drawn from the indwelling catheter but not in peripheral blood, a suppurative wound site, fungemia, and the isolation of certain bacteria such as coryneform bacteria of the JK group.

It is unclear whether or not the presence of bacteremia predisposed this patient to disseminated aspergillosis. Of note, however, the chest x-ray suggested disseminated aspergillosis as early as the day of the positive bacterial blood culture. In approximately 50% of cases of invasive aspergillosis in immunocompromised patients, there is another associated infection. Usually this is with such organisms as *Pseudomonas aeruginosa, Candida albicans* or *E. coli.* The association of aspergillosis with coryneform bacteria has not heretofore been documented.

In the immunocompromised host, infection with *Aspergillus* species is frequently a fatal disease. Less devastating forms of *Aspergillus* infection, such as allergic pulmonary aspergillosis, or aspergilloma, occur infrequently in this population. In the compromised host, invasive infections with *Aspergillus* invariably involve the lungs. The picture in the lungs can be that of a hemorrhagic bronchopneumonia (30%), multiple vascular infarcts with hemorrhagic necrosis (30%), or pulmonary abscesses (20%). This patient had the first two of these patterns. The disease is characterized by rapid progression to death. In one series, 20% of patients with invasive pulmonary aspergillosis progressed from a negative chest x-ray to death within a one-week period.[1] Widespread dissemination occurs in approximately 50% of cases. Multi-organ involvement in this case included kidney, pericardium, diaphragm and skin. Other organs frequently involved with metastatic, blood-borne spread include brain, intestines, thyroid and heart.

Treatment of disseminated aspergillosis seldom succeeds in patients lacking white cell reserves, particularly if the initiation of treatment is delayed.[7,8] The extent of this patient's infection, in face of total obliteration of his bone marrow, could not be overcome by antifungal chemotherapy. Amphotericin B was begun within 48 hours after the chest x-ray suggested a fungal disease; thus, in this case, prompt and appropriate therapy had no effect on outcome. If *Aspergillus* infection were more strongly suspected at that time, higher dose amphotericin B might have been used, and a possibly synergistic drug such as rifampin might have been added to the regimen. However, there are no data to prove that any antifungal combination therapy improves the outcome compared with amphotericin B alone.

Because of the futility of our present therapeutic regimens against fullblown infection with aspergilli, attempts have been made to diagnose cases earlier. Numerous serologic tests have provided inconsistent results; most have been insensitive, with false-negative rates as high as 50%. In one study positive serologic tests for aspergillus antigens correlated with the presence of invasive aspergillosis in susceptible patients.[9] Another technique under investigation for early diagnosis incorporates surveillance cultures of the nose;[10] in the National Cancer Institute at the University of Maryland Hospital, this technique predicted subsequent infection in 10 of 18 patients who developed clinically significant disease. However, nasal cultures were negative in eight patients who developed invasive disease. Thus at present, neither prospective serologic tests nor surveillance cultures can be recommended in monitoring of granulocytopenic patients in the general hospital setting.

This case illustrates the infectious complications of antileukemic therapy. New organisms such as multiply resistant bacteria and fungi, as well as viruses and mycobacteria that are resistant to conventional antibiotic therapies, are being selected as opportunistic pathogens. Clinicians must be aware of the risks of broad-spectrum antimicrobic therapy that predisposes such patients to colonization with nosocomial organisms. When infection develops, every attempt should be made to identify the pathogen involved, so that appropriate and narrow-spectrum anti-infective therapy can be administered. Nonetheless, even with effective antimicrobic agents, the outcome frequently is determined by whether or not the granulocytopenia is reversed.

Final Pathologic Diagnoses: Erythroleukemia, treated (clinically evolving from preleukemia). Invasive aspergillosis, involving lungs, pericardium, diaphragm, kidney and skin.

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Important Advances in Clinical Medicine

Epitomes of Progress—Occupational Medicine

The Scientific Board of the California Medical Association presents the following inventory of items of progress in occupational medicine. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in occupational medicine that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Occupational Medicine of the California Medical Assocation and the summaries were prepared under its direction.

Irritant and Sensitization Effects of Formaldehyde

Clinicians not uncommonly encounter patients with concerns about the relationship of a variety of subjective symptoms and formaldehyde exposure and sensitivity at home or in the workplace.

In October 1983 the Consensus Workshop on Formaldehyde brought together scientists from academia, government and industry to address the toxicology of formaldehyde. The workshop's panel on Immunology, Sensitization and Irritation reaffirmed that irritation of the eye and upper respiratory tract occurs but that a population threshold for this effect does not exist. Some sensitive persons may have sensory irritation at formaldehyde concentrations as low as 0.03 ppm, though most do not until levels are greater then 0.1 ppm. The ability of formaldehyde to produce skin irritation and allergic contact dermatitis was affirmed. Formaldehyde-induced contact urticaria has been documented on both an immune (type I allergy) and nonimmune basis. The workshop did not feel that sufficiently well-controlled scientific studies were available to establish that respiratory tract sensitization to formaldehyde occurs.

Pulmonary sensitization to formaldehyde may occur but is probably rare. In 1984 Reed and co-workers published a report of 13 patients with symptoms suggestive of asthma who had been exposed at home or work to formaldehyde ranging from 0.1 to 1.2 ppm. On bronchial challenge with 0.1, 1 and 3 ppm of formaldehyde for 20 minutes, no patient showed a significant (20% or greater) decline in forced expiratory volume in one second over 24 hours. Similar findings have been noted in persons with asthma, suggesting that even in preexisting asthmatic conditions formaldehyde at these concentrations fails to induce bronchial hyperactivity on an irritant basis. These reports contrast with that of Nordman and colleagues in 1985. A total of 230 patients occupationally exposed to formaldehyde was referred to the Institute of Occupational Health from all over Finland. Detailed medical and occupational histories were taken, spontaneous diurnal variations of peak expiratory flow were recorded and spirometry with bronchodilator, histamine provocation tests and bronchial challenges with 1 to 2 ppm formaldehyde and placebo were done. Of the 230 patients, 12 were considered to have bronchial asthma specifically caused by formaldehyde.

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Reprinted from *The Western Journal of Medicine*, October 1985.

Evaluating Infertility—Occupational Dangers to the Male Reproductive System

In an earlier issue of the journal, Becker described male reproductive hazards, and this topic was later extended to workplace exposure. I will discuss two generally accepted approaches to evaluating gonadotoxic effects of occupational agents: assessing sperm quality and monitoring worker reproductive history by a brief questionnaire.

Full clinical assessment of sperm quality involves consideration of many complex factors. Examination of one of these factors, sperm count, has been the major sperm-related method for evaluating the workplace for gonadotoxic agents. As described by Whorton and coworkers, however, the method is psychologically invasive because one or more sperm specimens are required for analysis. Other important limitations and methodologic problems are discussed by limitations and methodologic problems are discussed by Milby and Whorton. The method's principal advantage is that combining sperm count data with environmental exposure measurements often shows recent contact with gonadotoxic agents.

Worker reproductive history is monitored by a questionnaire. This method involves retrospectively computing a standardized fertility ratio (SFR) derived from data on national birth probabilities. The SFR describes fertility before, during and after gonadotoxic exposure and differences are identified between exposed and nonexposed groups. A major advantage is its essentially noninvasive nature: questionnaire responses are limited to psychologically benign factors such as marital status, date of marriage and number, age and sex of children. Levine and colleagues have validated this method among workers exposed to dibromochloropropane and concluded that the questionnaire technique would have identified damage to the male reproductive system a number of years earlier than did the sperm count method.

Both methods generate valuable screening and evaluation data. The major differnce is that the sperm count method is more useful for identifying recent gonadotoxic exposures, whereas the questionnaire approach provides a retrospective picture of male reproductive system damage. Both methods, however, provide useful tools for assessing the gonadotoxic potential of a workplace.

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Silicosis and Cancer Risk

Although the association between asbestos exposure and lung cancer has been well documented, silica exposure has not generally prompted concern about the excess risk of lung cancer. Recent evidence from both epidemiologic investigations and studies using animals has stimulated renewed interest in this association.

The findings of several studies of miners and foundry workers suggest that they have an excess risk of lung cancer. Those with relatively heavy exposure, such as furnace bricklayers and fettlers, appear to have the highest risk of excess lung cancer deaths. The specific role of silica is difficult to interpret, however, in that foundry workers are exposed to several potentially carcinogenic agents, such as polycyclic aromatic hydrocarbons (PAH), other organic compounds and metals such as lead, chromium and nickel. Some recent data suggest that there may be a synergistic interaction between silica and PAH in increasing the risk of lung and urogenital cancer. There is one group of workers, Vermont Granite workers, who have a relatively isolated exposure to silica dust. Data from a 30-year cohort study of mortality in these workers suggest a slight but not significant increase in the incidence of cancer of the respiratory and gastrointestinal tracts and prostate and no relationship between amount of silica exposure and cancer risk.

Recent studies in animals suggest that silica alone may be a carcinogen. It appears that lifetime studies may be necessary to show tumorigenesis; perhaps this is why the association between silica and cancer has not been appreciated in earlier studies of experimental silicosis. Adenocarcinomas and squamous cell carcinomas have been induced in rats after either inhalational exposures or intratracheal instillations. Histiocytic tumors have been induced in rats by intrapleural inoculation of silica, which has also been found to act as a cocarcinogen with benzpyrene.

In summary, then, if there is an increased risk of lung cancer from silica, the risk is probably small and will be very difficult to prove conclusively. Important confounding variables in epidemiologic studies include smoking history, the concomitant presence of nonmalignant respiratory tract disease and occupational exposure to other dusts and carcinogens. Though studies in animals suggest that silica may be a carcinogen, there is a long latency, relatively heavy exposure may be necessary to elicit tumorigenesis and species specificity may be significant. Whether silica acts as a carcinogen alone, as a cocarcinogen or in some other capacity to enhance the risk of lung cancer remains to be determined. As new data emerge, evaluation of silica exposure standards may need to take into account the role of silica exposure in lung cancer risk.

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Surveillance of Hospital Personnel Exposed to Cytotoxic Drugs

Many cytotoxic drugs have been shown to be carcinogens or mutagens. In recent years, there has been a pronounced increase in the use of cytotoxic agents in treating cancer patients and, infrequently, patients with collagen diseases and psoriasis. In some patients who have had cytotoxic therapy, new malignant tumors have developed. Exposure to these drugs may prove to be occupationally health-hazardous in the case of certain hospital workers. Hospital pharmacists are involved in handling and preparing cytotoxic drugs, nurses and physicians in their administration and housekeeping staff in disposing of drug residues and products.

A few studies have been conducted relating chronic daily exposure to small amounts of these drugs to possible mutagenic or carcinogenic effects in the population at risk. Two methods have been used in assessing exposure to the cytotoxic drugs. First, the measurement of mutagenic activity in urine and, second, chromosome analysis for sister chromatid exchange and other chromosome aberrations of peripheral lymphocytes. Most studies indicate that personnel who were exposed to cytotoxic drugs had a greater number of chromosome abnormalities and increased sister chromatid exchanges or an increase in urine mutagenic activity.

Although these methods of assessing exposure to cytotoxic drugs have their limitations, and while better surveillance tools are yet to be developed, these findings suggest the need for better precautionary measures to control unnecessary occupational exposures. Several quidelines have been developed concerning work with cytotoxic drugs. The principles of minimizing occupational exposure include good operational practice: the wearing of personal protective equipment (gloves, masks and clothing), the use of biologic safety cabinets (vertical laminar flow-containment hoods and bacteriologic glove boxes) and the proper labeling and disposal of cytotoxic waste products. Despite the use of precautionary measures, there is always a possibility of system failure and consequent exposure. Therefore, the need for biologic surveillance exists. Because of the large variability among persons, preemployment baseline measurement of sister chromatid exchange or urine mutagenicity may be more meaningful for exposure assessment to cytotoxic drugs than comparison of test results with normal population values.

The long latency period for the development of most cancerous lesions necessitates, doing large-scale retrospective or prospective studies to determine cause-effect relationships between exposure and carcinogenesis. In the meantime, appropriate control measures should be exercised to protect hospital personnel who have significant daily occupational exposure to these medications. Other things being equal, the degree of exposure is a function of the amount of material being handled. Cytotoxic materials are handled in hospitals, free-standing clinics and physicians' offices.

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Video Display Terminals and the Eye

The public press has suggested that many adverse medical effects occur from the use of video display terminals (VDTs). It has been reported the VDTs adversely affect the outcome of pregnancy and cause orthopedic and ocular problems, as well as possibly other problems. Only ocular problems will be dealt with in this article. The following paragraphs are modifications from a paper prepared by the American Academy of Ophthalmology.

A number of studies have been made by scientists at the Food and Drug Administration's Center for Radiological Health and Devices, Bell Laboratories and the National Institute of Occupational Safety and Health. The data from their work indicate that the VDTs "emit little or no harmful ionizing (eg, x-rays) or noionizing (eg, UV [ultraviolet]) radiation under normal operating conditions." The emissions that were detectable were all well below the current national and international safety standards and were no greater than those produced by fluorescent lighting. In fact, the amount of ultraviolet radiation produced by VDTs is a small fraction of that produced by fluorescent lighting.

As for ocular damage, the best available current experimental and epidemiologic evidence does not indicate, or show, that the level of ultraviolet radiation emitted by VDTs is capable of exerting any deleterious effects on the ocular lenses of personnel using their terminals. Further, our own cornea and lens serve as natural filters for ultraviolet radiation, thereby protecting the retina, which is sensitive to low-level ultraviolet radiation.

Although there is no evidence that VDTs cause permanent ocular damage, in some work environments their use is associated with complaints of physical discomfort. These include ocular irritation (red, teary or dry eyes), fatigue (tired, aching heaviness of the eyelids), difficulty focusing (blurriness for seeing near or far objects), headaches, backaches and other musculoskeletal discomfort. Studies, particularly in Europe, indicate that most of these problems are related to poor ergonomic design of the workplace, lack of attention to the lighting and reflectance level of work surfaces, the type and intensity of the job demands and the quality of the video display. These can be alleviated by having the seating, angle of the VDT and so forth adjustable to each worker's comfort needs; by adjusting the lighting to minimize glare; by using high-quality monitors whose contrast and brightness can be controlled by the operator, and by making provisions for periodic rest breaks. In addition, eyeglasses worn by the workers, particularly those 40 years and older who have a reading or bifocal section, may need to be adjusted for the distance at which they view the VDT.

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Chronic Encephalopathy From Organic Solvents

Acute symptoms from organic solvent exposure resemble intoxication, ranging from simple depression or loquacious euphoria to slowed reflexes, dysarthria, dizziness, nausea, confusion, ataxia and even coma. Recurrent symptoms of intoxication associated with solvent exposure suggest the presence of chronic toxic encephalopathy analogous to that seen with long-standing ethanol abuse.

With repeated significant exposure, cumulative neuronal damage will produce gradual clinical manifestations of short-term memory loss, irritability, personality change, lethargy, impaired learning, impaired perception, depression and social withdrawal, all of which reflect a loss of cognitive abilities. There may be a history of eliminating or drastically reducing alcohol intake because of symptom exacerbation. Affected persons may frankly admit their diminished capacities or may confabulate or alibi to cover embarrassment. Although slowed peripheral nerve conduction can often be shown by measurement, clinical symptoms of peripheral neuropathy are less common. Dexterity and balance maintenace may be impaired.

Diagnosis requires recording the degree and pattern of cognitive impairment, and for this there is no substitute for the neuropsychologic test battery administered by a psychologist aware of the possibility. The standard clinical neurologic examination usually gives normal results, except for those responses that suggest impaired mentation. Electroencephalograms are usually normal. Advanced cases often show reduced cerebral size on a computed tomographic scan.

The prognosis is grim, especially if the offending exposures have happened over a considerable time period. Rehabilitative efforts can aid in coping with the problems of living. Investigators in Sweden have found that solvent-induced encephalopathy has ocurred even though the solvent exposures were within the recommended limits. Because of the similarity of the clinical pictures, cases of presenile dementia should be screened with a careful occupational history in a search for chronic solvent encephalopathy.

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Cataracts, Ultraviolet Light and Occupational Exposure

Over the past ten years, there has been a growing recognition among ophthalmologic scientists that a major factor in the progression of the cataract of advancing age is ultraviolet radiation exposure.

The origins of this concept are based in epidemiologic investigations. In the 19th and early 20th centuries, Gross and Schulek first observed that cataracts were more common among people working in fields than in cities. This was confirmed by ophthalmologists in Hungary, Germany, Romania and Egypt. Furthermore, in dwellers near the equator (India, Pakistan, Africa and Central and South

America) cataracts occurred earlier and at greater frequency when compared with those in the temperate zones of Europe and North America. Current studies add to the evidence. In the 1970s it was reported that cataracts occur earlier and more often in persons in Israel and India than in those in England or Scotland. In the United States, Hiller and colleagues reported that cataract prevalence is correlated with the number of hours of daylight determined from weather maps. Zigman and associates studied three geographical areas and showed that where the sunlight is brightest, brown cataracts occur at a higher frequency. In workers exposed to sunlight (farming, fishing, truck driving and construction) nuclear brunescent cataracts were found to develop much more frequently than in those who worked indoors. An analysis of 100,000 Australians (Aborigines and whites) recently showed a clear correlation between the prevalence of senile brunescent cataracts and levels of ultraviolet radiation.

Long-wave or near-ultraviolet light (300 nm to 400 nm) is now known to damage the ocular lens by inducing molecular changes in its proteins and by causing cytopathologic changes in its constantly actively growing epithelial cells. Laboratory studies have elucidated the molecular basis of sunlight-induced cataracts. Photon absorption by aromatic amino acids in lens proteins, particularly tryptophan, has been shown to be an initial event. Abnormal pigments with decomposed tryptophan accumulate as a brown, nuclear cataract. On the other hand, cortical cataracts may have a different pathogenesis, involving photolysis of membrane transport enzymes.

The inclusion of an ultraviolet-blocking molecule in the lenses of safety or operating-driving glasses would be effective prevention. There are 111 million American workers in occupations with cataract-inducing levels of ultraviolet exposure.

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Melanoma—An Occupational Hazard?

The reported incidence of skin melanoma is increasing among fair-complexioned people throughout the world. The increase is seen primarily between latitudes 45° north and 45° south. Higher levels of education and socioeconomic status, an indoor occupation, skin that sunburns easily, a history of melanoma or other skin cancer, dysplastic nevi and an increased number or size of moles are factors that correlate with melanoma incidence and in this sense may be thought of as "risk" factors.

Occupational factors have also been suggested as being contributory. However, when these suggested factors are examined among employee groups with comparable occupational exposure but in different geographic locations, consistency is lacking. At the First International Conference on Skin Melanoma, held in Venice in May 1985, neither the presentation of "Environmental Factors in Melanoma" by J.A.H. Lee, nor the subsequent discussions among the world experts in attendance implicated occupational factors as causal.

This leaves those concerned with melanoma the challenge of identifying factors possibly contributing to the increased frequency of melanoma diagnosis and of documenting possible causal relationships. Every practitioner of medicine must be vigilant in scrutinizing the skin of high-risk patients and seizing opportunities for the earliest possible detection of melanoma. Complete removal of thin lesions is almost always curative. Patient education is the cornerstone of early detection and consequent saving of lives.

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The Occupational History

Many articles on occupational medicine remind physicians in other fields of the necessity of taking a good occupational history along with the medical history. Towards this end, various formats and styles of history taking are presented in the literature. Most tend to be highly inclusive, complex and cumbersome to use in daily practice. At the other extreme, a physician who does not use any routine or format may be lost early on and abandon the quest for occupational illness after the single inquiry, "What kind of work do you do?" And, finally, unless familiar with the field and legal requirements, many will not know what to do with the information gathered by using most available formats. The following format is presented to aid physicians both in taking a history and in directing them in the use of the information. The form should be used following a work history and positive response to general inquiry of exposure to substances and workplace environments such as asbestos, heavy metals, carcinogens, pesticides, noise, solvents, arsenic, ethylene oxide, dusts and radiation.

The format provides space for a general work description, exposure data and legal limits of toxic substances and required health surveillance in California. This format can be tailored to a particular area or population by adding or deleting specific exposure categories. It is best used when provided to patients in advance of their appointment so that reference can be made to work records for accuracy. However, it can also be used effectively when completed in the waiting room and reviewed with the examining physician at the same visit. It is most effective if maintained and compared from year to year on subsequent visits. The form is entitled "Interim Toxic Exposure Questionnaire" and was developed for and is currently in use in periodic health surveillance examinations of the California Occupational Safety and Health Administration (Cal/OSHA) industrial hygiene and safety engineer inspectors by participating physicians at eight clinics throughout California.

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The Health of Refugees and Employment

In the wake of continuing civil and military strife and suppressive behavior by governments around the world, there has been an upsurge in immigration to the United States. In the two-decade span since 1961, a total of 7,815,000 people came to this country; in the five years from 1977 through 1981 alone, 2,651,000—or 34% of the total—arrived. Of particular health concern have been the more than 670,000 refugees immigrating since 1975 from Southeast Asia.

A variety of conditions has been documented at centers where numbers of refugees have been diagnosed and treated, including hepatitis B antigenemia, tuberculosis, parasitism (often with several agents), anemia, malnutrition, gonococcal infections and Hansen's disease. Internment before entry into the US has led to further health impairment. Subsequent study has disclosed primary resistance to antituberculosis drugs among Indochinese, the sudden unexplained nocturnal deaths among previously healthy men, dental problems, unfavorable pregnancy outcomes and a lack of understanding in the health care system of indigenous beliefs and practices involving self-care and attitudes toward, and expectations of, Western medicine.

While many of the immigrants have established their own businesses in big city enclaves, others have entered the labor market. With the passage of time and the acquisition of citizenship status, it is likely that there will be applications for employment among this group in manufacturing companies engaged in defense production. Both inplant health services and physians conducting preplacement examinations should add certain case-finding procedures to their examination protocols that ordinarily are not included in the prehire evaluation or are not indicated in today's medical reviews of most job candidates.

The following procedures are suggested as components of the preplacement examination of refugees, particularly of those persons from Southeast Asia:

- A general physical examination.
- Tuberculin skin testing with subsequent chest radiography of persons having positive skin reactions. Referral to local or state health departments should be effected for the initiation of therapy. The Centers for Disease Control recommend further that a bacteriologic examination with smear culture and susceptibility studies be done in all suspected or follow-up cases.
- Serologic test for syphilis.
- Serologic test for hepatitis with forwarding of results when sources of general health and dental care have been established by the applicant or employee.
- Stool examination for intestinal parasites.
- Thick and thin blood smear tests for malaria for all persons with fever.
- Immunizations—tetanus toxoid, trivalent oral polio vaccine and others as indicated by age, previous immunization history or job assignment.

Particular clinical scrutiny must be conducted of food handlers, and appropriate treatment regimens initiated if parasitism involving *Giardia* and *Entamoeba histolytica* is encountered. Hepatitis B in a food handler presents a public health risk.

Certain culturally offensive practices should be avoided in the health assessment of Southeast Asian refugees:

- Complete disrobing of female patients (applicants or employees).
- Pelvic examination. This is usually not included in occupational medical practice, but, if indicated, it is not to be carried out on the first contact, and preferably should be done by a woman physician.
- Visible presence of an interpreter of the opposite sex during a breast or gynecologic examination.
- Negative judgmental attitudes toward traditional healing practices.
- Withdrawing numerous tubes of blood without proper warning or explanation.

As employment implies future visits to an occupational health facility, strict adherence to these recommendations will allow the establishment of trust and will ease further contacts required by either illness or surveillance programs.

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Health Risks in the Operating Room

Although health risks to patients undergoing surgical procedures have been widely recognized for many decades, it is only since the 1970s that the health risks to workers in the operating room have received similar attention.

There are several possible sources of health risk to operating room-based personnel. The most studied source is pollution from gases, which include volatile anesthetics, methyl methacrylate (used in surgical cements) and various sprays. Although more speculative, other sources include ionizing radiation, infection and stress. While causal relationships have not been firmly established, chronic exposure to anesthetic gases is most often implicated as the etiologic agent of increased risk.

Epidemiologic studies have identified several possible health hazards to operating room personnel. The most widely studied effects deal with reproductive outcomes. For example, it is generally accepted that female staff working in the operating room have a spontaneous abortion rate about twice that of various control groups. The results are equivocal for the wives of exposed male staff. Similarly, there are conflicting results concerning other reproductive outcomes such as congenital anomalies in offspring, sperm abnormalities, infertility, stillbirths and altered sex ratio.

Other health risks associated with operating room exposure include cancer (such as leukemia and lymphoma), hepatic disease (besides hepatitis B), suicide and impaired psychomotor abilities. Again, these results are not consistent among the various studies and the case for increased risk has not been proved.

Unfortunately, many of these epidemiologic studies suffer from similar shortcomings—namely, their retrospective design, heavy reliance on questionnaires and grossly inadequate exposure data. Moreover, many studies were done before the use of newer anesthetic agents and modern gas scavenging systems. Thus, only a few associations appear to be valid today and contemporary, well-designed studies are warranted.

Nonetheless, recently developed technologies should be used to reduce the health risks to these workers. Specifically, personal dosimeters for gases and radiation should be used. In addition, protection from ionizing radiation (including thyroid shields and leaded glasses) should be available and the ambient levels of trace anesthetic gases in the operating room should be evaluated and minimized. Clearly, continued monitoring of these health workers is justified.

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Use of Personal Respiratory Protective Devices (Respirators)

"Can this worker safely use a respirator?" is a question that clinicians are frequently asked. While it would be optimal to eliminate or completely enclose all workplace inhalational hazards, it is frequently necessary to rely on respirators worn by a worker for protection. These devices range from simple disposable filter masks to complex, heavy, self-contained breathing apparatuses such as those used by fire fighters.

Several factors affect medical fitness for using respirators. Certain physical characteristics such as weight may preclude their use. Certain respirators may impose loads on the respiratory or cardiac systems or both. A recent report suggests that as much as 10% of workers may have psychological problems regarding their use. The use of contact lenses while wearing respirators needs careful consideration. Finally, appropriate safety orientation and a worker's knowledge of the chemical hazards to which she or he is exposed is important. The recently enacted federal Right to Know Law mandates such worker training about chemical hazards for workers in many industries.

Fortunately, most respirators are well tolerated by most workers, and an extensive medical evaluation is rarely needed. Clinicians can frequently obtain information about respirators and the hazards against which they protect from a plant's occupational health service or industrial hygienist. Governmental (such as the Occupational Safety and Health Administration [OSHA]) and private or university consultants can also be of help. Finally, directly observing a worker using the respirator may be invaluable.

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Employee Drug and Alcohol Abuse—Industry's Approach

The annual cost to industry of employee drug and alcohol use has been estimated at as high as $16.4 billion. A confidential mail survey of national organizations conducted in 1981 found that 80% of the respondents had to deal directly with drug problems. While alcohol was the most commonly abused substance (82%), marijuana incidents occurred in more than half the firms (55%) and both heroin and cocaine use was reported by a fifth of the organizations. The survey confirmed that drug usage in the workplace is relatively widespread and is not confined to blue collar or minority groups.

Employers use a variety of means to combat employee drug and alcohol use. A prerequisite to any technique is the development of a company policy outlining an organization's position on drug and alcohol abuse. The most widely accepted procedure is the establishment of an occupational treatment program whose primary target is workers whose job performance is impaired. This employee assistance program is a confidential service that intervenes with troubled workers, whether self or supervisor referred. It assumes that an employee's value to the organization is based on substantial training and time investment, a value that frequenly does not extend to the youthful abuser. Young employees, having a different work ethic, do not respond favorably to constructive confrontation. Intervention varies with the particular program from simple triage to diagnostic evaluation, motivation, referral and follow-up. The treatment—normally subsidized by the company but provided at an accredited treatment facility not usually affliliated with the firm—is considered a condition of continued employment. Most employee assistance programs, however, reach only 5% of the target population.

Another method of providing a drug-free workplace involves urine drug screening on all employment applicants and selective screening of suspected abusers. Urine toxicology screening is an effective test to determine the presence of drugs in the urine. Thin-layer chromatography and radioimmune assays or modified techniques, such as the enzyme multiplied immunoassay technique, test for a wide spectrum of drugs including marijuana, phencyclidine hydrochloride, heroin, opiates and amphetamines. A great deal of weight is often placed on positive findings; however, the test does not provide information about the pattern of use and cannot distinguish between an occasional user and a chronic abuser. The cost-effectiveness of this approach can be improved by limiting the tests based on the results of the preemployment medical examination.

There are serious questions about the reliability of the results of screening urine for drugs. In a recent evaluation of the performance of 13 laboratories, error rates for barbiturates, amphetamines, methadone, cocaine, codeine and morphine ranged from 11% to 94%, 19% to 100%, 0% to 33%, 0% to 100%, 0% to 100% and 5% to 100%, respectively. False-positives ranged from 0% to 6%, 0% to 37%, 0% to 66%, 0% to 6%, 0% to 7% and 0% to 10%, respectively. These results suggest the need for monitoring the performance of organizations and contract laboratories with blind quality-control samples. All urine toxicology screening tests require confirmation by an alternative method before being considered positive. Where punitive action is contemplated, additional tests may be necessary to accurately quantify urine and serum drug levels.

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AIDS—Management of Hazards to Health Care Personnel

All patients with the acquired immunodeficiency syndrome (AIDS) will require hospital or outpatient care or both during their illnesses. A wide variety of health care personnel, therfore, face emotional and infection hazards that must be carefully addressed. In addition, Centers for Disease Control (CDC) surveillance has shown that 3% of patients with AIDS are health care personnel (although none has been "linked to a specific occupational exposure"). Special attention must be given to these workers and to (1) those in AIDS risk groups because of life-style and (2) those who have other immunosuppressing conditions.

Available evidence about human T-cell leukemia virus III transmission has led to the design of infection control guidelines very similar to those for hepatitis B. Highlights include the following:

- Assume that every patient has *some* occult infectious disease.
- Slow down and *think* when using, manipulating or disposing of needles.
- Wash hands, even when gloved.
- Wear protective eye wear during suctioning or endoscopy if aerosols or flying debris may be produced.
- Disinfect surfaces with a bleach solution (1:10).
- Reevaluate requirements for mouth-to-mouth practice during cardiopulmonary resuscitation (CPR) certification and have resuscitation bags and airways immediately available for AIDS patients who desire CPR.
- Follow established hepatitis B protocols after AIDS exposures and give indicated hepatitis B prophylaxis without delay.

Support of staff members who may be fearful, exhausted, uninformed or grieving is as important as infection control. Fortunately, hospitals have social workers, chaplains, psychiatrists and psychologists and access to outside groups and can therefore design educational and counseling programs for individuals and groups. Additionally, policies must be designed to address the special requirements of pregnant personnel and immunosuppressed employees with patient care or particularly demanding responsibilities. Finally, confidentiality must be respected.

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Informed Consent:
Are "Miracle, Mystery and Authority" Better Medicine?

JAY KATZ, M.D.

A fundamental tension inherent in the physician-patient relationship—the tension between patient choice and physician paternalism—was vividly portrayed by Dostoyevsky in the encounter between the Grand Inquisitor and his Prisoner, the son of God. Only the Grand Inquisitor spoke; his Prisoner remained silent throughout.

> Look what you have done . . . in the name of freedom! I tell you man has no more agonizing anxiety than to find someone to whom he can hand over with all speed the gift of freedom with which the unhappy creature is born. [For, it is] the nature of man [that he cannot] reject a miracle at the most fearful moments of life [and] stick to the free decision of the heart. [M]an is unable to carry on without a miracle, [and] he will create new miracles for himself, miracles of his own, and will worship the miracles of the witch-doctor and the sorcery of the wise woman . . . . We have corrected your great work and based it on *miracle, mystery,* and *authority.* And men rejoiced that they were once more led like sheep and that the terrible gift [of freedom] which had brought them so much suffering had at last been lifted from their hearts . . . . Tell me. Did we not love mankind when we admitted so humbly its impotence and lovingly lightened its burden . . . ?[1]

Since the days of Hippocrates, many physicians have shared the Grand Inquisitor's view of the limitations of human nature. This view has shaped the conversation between doctors and patients in powerful and self-fulfilling ways.

In theory, the legal doctrine of informed consent opposes this view, by asserting that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body . . ."[2] Such a right, of course, makes sense only if it rests on the assumption that at least some human beings are not "sheep," are willing to accept "the terrible gift of freedom," and welcome making their own choices. But does this assumption hold true, for human beings in general, and more importantly for us, does the assumption hold true once human beings become patients? This question has provoked considerable controversy since the birth of the doctrine of informed consent. Opponents have insisted that patients have little capacity to make their own decisions and that asking them to do so is bad medicine.

I shall leave unexplored the question of whether patient self-determination or physician reliance on miracle, mystery, and authority are better medicine, even though I chose it as the title for my remarks. The choice was deliberate. I wanted to highlight that this question cannot be answered. All answers, given so far are based on dubious data. The question will only be answered once medical scientists consider it worthy of scientific study. It is surprising and telling that such studies have not been undertaken, even though our ignorance of the answer to the question—what is the better medicine?—precludes a fuller understanding of the most significant concern in our professional work: the dynamics of cure.

I intend to demonstrate that we have to begin *de novo* and, therefore, will discuss with you the ignorance, confusion, incoherence, and self-deception that underly all the current talk about patient participation in decision making, now subsumed under the rubric of informed consent.

The confusion begins by not distinguishing between three fundamental aspects of informed consent: first, the *idea* of informed consent (based on the yet unproven belief that patients can play a greater role in medical decision making); second, the *legal doctrine* of informed consent (which endorses, although ambivalently, this belief); and third, *current practices* of obtaining informed consent, (still so thoroughly shaped by professional beliefs in the wisdom of delegating decision making to doctors). Physicians are instinctively aware of the confusion when they simultaneously express doubts about the idea of informed consent, complain of not knowing what to tell and what to withhold in order to comply with the legal doctrine, and profess compliance with both the idea and the legal mandate in their clinical practice.

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What underlies the confusion, incoherence, and self-deception is that neither medicine nor law have taken the idea of informed consent seriously enough to answer the fundamental questions raised in the encounter between the Grand Inquisitor and his Prisoner: Are *patients* capable of giving, and willing to give, consent (the most frequently asked question); are *physicians* capable of making, and willing to make, disclosures that allow patients to give meaningful consent (a question infrequently asked); is the *science of medicine* sufficiently advanced to permit physicians to make adequate disclosures and, in turn, to obtain patient consent (a question virtually never asked).

I have been a student of informed consent for decades. One of the few *definitive* conclusions that I have come to is this: Neither its champions nor its critics sufficiently appreciate the complex nature of the problems that make informed consent so difficult to obtain. Let me mention in passing that critics of my work have overlooked that I have only championed *the idea* of informed consent, have written mainly about the obstacles that make the idea of informed consent so difficult to implement. I have not proposed an informed consent doctrine of my own. While, to the contrary, many doctors, lawyers, judges, and bioethicists have spoken about informed consent as if they knew what it meant either in law or in medicine, they have at best proposed *their* own doctrine. *The* doctrine cannot be discerned by looking to law or medicine.

You might be puzzled and ask: Is there not a legal doctrine of informed consent that can guide physicians' conduct? My answer is "no;" it cannot even guide judges' holdings. This for two reasons:

First, the legal doctrine is, and always has been, in disarray. Consider its first formulation: "[I]n discussing the element of risk a certain amount of *discretion* must be employed consistent with the full *disclosure* of facts necessary to an informed consent."[3] The disarray is, in part, a result of the existence of many legal doctrines, depending on the jurisdiction in which they were promulgated. Further, the legal doctrine attempts to reconcile conflicting interests and values in the law of torts: respect for patient self-determination and autonomy; protection of patients from "ill-considered, autonomous" decisions that "prudent" patients would not make; protection of patients from the harm of disclosure; elimination of the requirement of expert medical testimony out of fear over a "medical conspiracy" of silence; and/or the allocation of the economic cost of injurious consequences to the one most capable of bearing the cost, *i.e.* physicians and their insurance carriers.

Second, the legal doctrine provides little guidance to doctors as to their general lawful disclosure obligations. To be sure, law generally defines only unlawful conduct. But the legal silence on a general medical disclose standard presents a dilemma, since disclosure and consent are concepts alien to medicine, and were imposed by law on medicine. Thus, questions arise: What must physicians learn to disclose to remain true to their professional obligations and at the same time avoid legal liability? Were judges obliged to learn more about the difficulties inherent in the practice of medicine before imposing foreign concepts on a profession that has little experience with disclosure and consent? As I have said in my book *The Silent World of Doctor and Patient*

> Judicial pronouncements calling for the revelation of "any facts [necessary to] an intelligent consent" confronted courts with the staggering assignment of specifying what these facts were. They would have had to address complicated questions involving sophisticated inquiry: What are the risks and benefits of the proposed treatment and of no treatment? Which ones did physicians have to be aware of? How much are they required to disclose? The courts were largely unwilling and unprepared to undertake this task. Instead, they retreated to the time-honored professional standard of care, which resurfaced in disguised form even in jurisdictions that had adopted the new legal rule of disclosure.[4]

The verdict is this: Courts did not delve into the complexities of medical practice to give physicians meaningful instructions about their disclosure obligations.

The incoherence created by side-stepping these questions is most clearly revealed in the division between courts which follow the *Natanson* line of reasoning, holding that "the duty of the physicians to disclose . . . is limited to those disclosures which a reasonable medical practitioner would make . . ."[5] and those which follow the *Canterbury* line of reasoning, holding that "[r]espect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians . . ."[6] The *Natanson* court, to underscore what I have already argued, overlooked that "a reasonable physician" has significant professional and personal reservations about disclosing a great deal to patients and, more importantly, that if a professional standard for disclosure exists at all, it is one that eschews disclosure. The *Canterbury* court's opinion, calling for a legal, rather than a medical, standard for disclosure and consent, can be easily misinterpreted, unless one keeps in mind that the court only set the limits of legal liability for *non-disclosure.* The opinion provided little guidance as to the *disclosure* standards physicians must establish for themselves in order to comply with the new and alien legal mandate.

This brief assessment of the current legal status of informed consent should not diminish the symbolic significance of judges' call for patient self-determination. However much judges and physicians might continue to try to evade, sidestep, and rationalize the complex questions posed by informed consent, the new doctrine prevents them from banishing certain fundamental questions completely from their consciousness: Do patients have a voice in decisions affecting their medical lives? If so, what must a physician communicate so that patients' voices will not remain hollow echoes of medical recommendations?

I now turn from law to our own practices. Before we can explore our own professional views on the nature and scope of patient participation in decision-making, we must appreciate that disclosure and consent except in the most rudimentary fashion are obligations alien to our thinking and practice. We have no experience with patient participation in decision making. We have no body of knowledge to fall back on. *De novo,* we have to begin the slow ascent from our feudal past which demanded that good patients follow doctors' orders without question.

The task that confronts us is to think deeply about the three major tensions that the implementation of the idea of sharing the burdens of decision with patients will create: The first tension is one of *authority.* Physicians throughout history have maintained that patients' needs are best served by following doctors' orders. Yet, the idea of informed consent demands joint decision making between physician and patient, a sharing of authority. Thus the question must be posed: Should either physician, patient, or both decide?

The second tension is one of *autonomy.* Meaningful decision making implies that both parties have the capacity to make choices. This notion is contrary to ancient medical beliefs that patients, by virtue of being ill, are more like children than adults and that therefore their capacity for choice is fatally impaired. Thus the question must be posed: Can anyone but a physician decide?

The third tension is one of *uncertainty.* Meaningful decision making requires that both parties have sufficient knowledge that can be imparted and understood. Medicine's vast ignorance about the etiology and treatment of disease places difficult, and at times insurmountable, burdens on physicians: first, to sort out for themselves knowledge from ignorance and, second, to communicate in a comprehensible fashion their certainties and uncertainties to patients. Thus the question must be posed: How can anyone, either physician or patient, make an informed decision?

Time does not permit me to address the barriers to informed consent created by our traditional notions of physician authority and patient lack of autonomy. I shall limit myself, and all too briefly at that, to the problem of uncertainty. I consider uncertainty the most formidable obstacle. If we wish to make meaningful disclosures to patients and obtain their consent, we must first learn to manage uncertainty better than we have in the past. Before listing a few of the problems that uncertainty poses for physician-patient communication and decision making, let me make one thing crystal clear: I do not want to suggest that all the issues I shall now raise deserve discussion with patients. I only want to suggest that we must clarify for ourselves *why,* in the face of uncertainty, we might wish to withhold certain information and *what* the implications of withholding information are for the informed consent process.

(1) Alvan Feinstein has noted that "at a time of potent drugs and formidable surgery, the exact effects of many therapeutic procedures are dubious and shrouded in dissension—often documented either by unquantified data of 'experience' or by grandiose statistics whose mathematical formulations are so clinically naive that any significance is purely numerical rather than biologic."[7] Must we communicate to our patients Feinstein's doubts about therapeutic efficiacy and, if so, how? If we do not, what is the meaning of informed consent?

(2) Lewis Thomas has called attention to how little we know and understand about nature, that "the only piece of scientific truth about which [we can feel] totally confident is that we are profoundly ignorant about nature."[8] At the same time, Thomas goes on to say, "we are at least facing up to [our ignorance]," and no longer need to make up "stories to fill the gap."[9] Since we are committed to the practice of scientific medicine, does this major achievement of medical science, i.e. the ability to distinguish better between medical knowledge and ignorance, oblige us to communicate both knowledge and ignorance to our patients? If we do not, what is the meaning of informed consent?

(3) We base so many of our interventions on "clinical judgment and experience," often in the absence of, or even in contradiction to, scientific proof. Must we communicate the experiential, scientifically unproven, assumptions that underly our recommendations to our patients? If we do not, what is the meaning of informed consent?

(4) In the treatment of breast cancer, as in many other therapies, controversy exists about the relative merits of various surgical treatments, chemotherapy, radiation therapy, hormone therapy or immunotherapy, or all of these in various combinations and permutations. Must we discuss these controversies with our patients and, if so, to what extent? If we do not, what is the meaning of informed consent?

(5) Specialization affects the choice of treatment. Must specialists inform patients that other specialists may treat their diseases differently even though their preferred treatment comports with acceptable medical practict? If we do not, what is the meaning of informed consent?

(6) Personal determinants affect treatment recommendations. A dramatic example to illustrate this point emerged in the reminiscences of George Crile, Jr. He remarked how for many years he had performed only radical mastectomies, while his father had always opted for a less mutilating surgical procedure. Once Crile, Jr. appreciated the errors of his ways, he asked himself: Was the "discounting of his father's ideas [a consequence of his] having been a rebellious child?"[10] Can we moderate these personal influences? Will "training for uncertainty" during medical school help? If we do not try to educate future physicians to manage uncertainty better, what is the future of informed consent?

(7) Physicians by-and-large prefer action to inaction, believing that errors of commission are less reprehensible than errors of omission. In the light of uncertainty about *vis medicatrix naturae,* the healing power of nature, vs. our interventions, particularly since the latter can ex-

pose patients to many iatrogenic complications, must we communicate the relative merits of intervention or delay to our patients? If we do not, what is the meaning of informed consent?

(8) Many of our interventions are elective and non-intervention is often an alternative. Must we more clearly distinguish between interventions that are elective and those that are mandatory, even when we believe that intervention is the better choice? If we do not, what is the meaning of informed consent?

(9) Time costs loom large in our reluctance to discuss uncertainty with patients. If we sacrifice information for the sake of time costs, whenever we believe that good medical care dictates taking the time, what is the meaning of informed consent?

I could go on, but I hope that I have said enough, to paraphrase Shakespeare, that there are more things in informed consent's heaven and earth than we have begun to contemplate. Hamlet, in gently chiding Horatio about his ignorance, ends by uttering the well-known words:

The time is out of joint: — O cursed spite,
That ever I was born to set it right! —
Nay, come, let's go together.[11]

Physicians generally believe that "the time is out of joint," and that informed consent is in part responsible for this state of affairs. I agree, but for a different reason. My reason is not that the world of medicine was a better one when doctors made decision for patients. My reason is that our world is out of joint because we too are uneasy about our traditional non-disclosure practices, yet feel so at sea about how to change them, how to reconcile societal with our professional obligations. Thus, we find our current communications unsatisfactory and wanting. This makes us anxious and in turn, angry. It should. We have been asked to assume, and we have assumed, a task that we cannot as yet perform according to the high standards of caring for our patients to which we are otherwise committed.

It is our *current* ignorance and incapacity, but not our *ultimate* ignorance and incapacity that I wanted to bring to your attention. "Cursed spite" notwithstanding, perhaps our generation and the next generation of physicians were "born to set it right." "Come, let's [do it] together," so that we can learn both to gain patients' trust and to trust them. Informed consent requires *mutual* trust. Without *mutual* trust it will remain a charade.

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CSMS 1986 LEGISLATIVE DIGEST

SHELLEY A. MARCUS, J.D.

The lawmakers have adjourned the 1986 Session of the Connecticut General Assembly after tackling many complex issues usually reserved for the long session. In the area of health and medicine, most of the lawmakers' time was spent on the issue of civil justice and insurance reform. The outcome was the passage of HB 6134, AN ACT CONCERNING TORT REFORM, aimed at making liability coverage available and at halting the rapid escalation of premiums where coverage does exist.

A series of wide-ranging civil justice reforms, advocated by CSMS, CBIA, the Insurance Association of Connecticut and CHA was approved by the General Assembly. In addition, many other bills of interest to the medical community were passed by the legislature. Many of these new laws are summarized for you in the "1986 LEGISLATIVE DIGEST." If you should have any questions or would like further information, please contact CSMS at 865-0587.

HB 6134—An Act Concerning Tort Reform

The primary focus of this year's legislative efforts was the passage of HB 6134. After more than 12 hours of debate in the House and Senate, and the defeat of at least twenty amendments, the General Assembly approved the bill. The new law was signed by the Governor on Friday, June 6 and will take effect on October 1 of this year.

Public Act 86-338 includes the following key provisions:

Section 1: CONTINGENCY FEES—Establishes a limitation on the amount an attorney may charge as a contingency fee in any civil action, claim or settlement of that action according to the following schedule: 33⅓% of the first $300,000; 25% of the next $300,000; 20% of the next $300,000; 15% of the next $300,000; 10% of any amount exceeding $1,200,000.

Section 2: PERIODIC PAYMENTS—Requires that future economic and non-economic damages in excess of $200,000 be paid to the plaintiff in installments. All past economic and non-economic damages (defined as all losses incurred up to the date of the award), litigation expenses and the first $200,000 of future economic and non-economic damages will be paid as a lump sum as under prior law. The payments will be made over a period of the lesser of 10 years or the life expectancy of the claimant, except that payments may be made over a longer period of time if the plaintiff consents and the court determines that such longer period is in the best interests of the plaintiff.

Section 3: JOINT AND SEVERAL LIABILITY—Prior law made an individual defendant liable for the entire damage award even though he may have been responsible for only a small portion of the injury. Under the bill, a defendent will pay only the percentage of damages for which he is found to be responsible. Thus, if a defendant is found to be 50% liable, he or she can only be required to pay 50% of the damage award.

However, if one or more of the defendants is insolvent, the remaining defendants will be liable for part of the uncollectible amount. For example, a defendant found to be liable for 10% of the damages would be required to pay his 10% plus 10% of the amount owed by the insolvent defendant. A party who pays more than his equitable share has the right to collect the amount of his extra payment from his co-defendant by bringing an action for "contribution."

Section 4-6: COLLATERAL SOURCES—Extends last year's medical malpractice collateral source offset to *any* lawsuit seeking compensation for personal injury or wrongful death. Those collateral sources which will be deducted from the final award include health insurance and similar benefits as well as any amounts received by the plaintiff as a settlement in the action. Life insurance, income disability insurance and wage continuation plans do not qualify as collateral sources.

Sections 8-9: EXPANSION OF GROUNDS FOR COUNTERSUITS—The bill permits a successful party in a civil action to request the court to make a finding that an action was brought without merit and not asserted in good faith. This finding will be admissible in any action brought for vexatious litigation. The bill loosens the restrictions on countersuits by allowing for double damages if an action is proven to be brought without prob-

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SHELLEY, A. MARCUS, J.D., Director of Government Affairs, Connecticut State Medical Society.

able cause and for triple damages if the action was brought without probable cause and with malicious intent.

Section 10: CIVIL IMMUNITY FOR OFFICERS AND DIRECTORS OF TAX EXEMPT ORGANIZATIONS—Any person who serves as an officer, director or trustee of a nonprofit organization, qualified under any section of 501(c) of the Internal Revenue Code, will be immune from civil liability unless the injury was caused by a willful or wanton misconduct of that person. This immunity from suit covers the Connecticut State Medical Society as well as any County Association qualified under Section 501(c) of the Internal Revenue Code.

Section 11: QUALIFICATIONS FOR EXPERT WITNESSES—This section sets standards for expert testimony against specialists and nonspecialists. An expert witness may not testify against a nonspecialist unless he is licensed in Connecticut or in another state with the same or greater licensure requirements. He must also have been active in the practice or teaching of medicine in the same discipline as the defendant within the five year period prior to the incident giving rise to the claim. In order to testify against a specialist, a physician must be board certified in the same specialty as the defendant and be trained and experienced in the same specialty. A physician may also testify against any defendant physician, whether specialist or nonspecialist, if he satisfies the court that he has sufficient training, as long as such training is a result of the active involvement in the practice or teaching of medicine within the five year period prior to the incident giving rise to the claim.

Section 12: CERTIFICATE OF MERIT—Prior to filing a medical malpractice case, the plaintiff's attorney will be required to make a reasonable inquiry to determine whether there are grounds for a good faith belief that the physician has been negligent. The attorney *must* then certify, on the complaint, that he has conducted such an inquiry and that the action is being brought in good faith. The attorney may satisfy this standard of good faith if he obtains a written opinion of a physician who meets the qualifications of an expert witness under this bill.

After the parties have completed discovery (i.e. depositions, interrogatories and other exchange of information), the court will determine whether the certificate of the attorney was made in good faith. If the court finds that the attorney did not act in good faith, the court shall impose an appropriate sanction upon the attorney, which may include the payment of expenses and reasonable attorney's fee to the defendant. The court may also submit the matter to the bar association for disciplinary review of the attorney.

Section 15: STUDY OF CAPS ON NONECONOMIC DAMAGES—Creates a Task Force to study various means of limiting noneconomic damages as well as other items of civil justice reform including alternative dispute resolution techniques, class actions, attorney's fees, expert witnesses and a victims' fund to account for insolvent defendants. A report is due no later than January 1, 1987.

HB 5858—An Act Concerning Studies of the Uniform Marital Property Act, The State's Judicial Court System, and Tort Recovery and Insurance Coverage

This bill creates a commission to study the Uniform Marital Property Act, the Judicial Court System and Tort Recovery and Insurance Coverage. The Commission consists of the following members: the co-chairman and ranking members of the Judiciary and Insurance and Real Estate Committees and four public members. The commission must issue a report to the General Assembly no later than February 1, 1987.

Licensure and Discipline

SB 94—An Act Concerning the Licensure and Discipline of Health Care Professionals Regulated by The Department of Health Services—Increases the power of the Department of Health Services (DOHS) in the area of granting licenses to all health care practitioners under its jurisdiction and expands the department's authority to take summary action against a provider's license or certificate. Specifically, the bill:

- Permits DOHS to deny a license or a permit to a health care practitioner as a result of certain actions such as being found guilty of a felony, being the subject of a pending or completed disciplinary action in another state, failure to comply with state laws governing his/her profession or fraud or deceit in procuring a license;
- Gives DOHS and health licensing boards a broad range of summary disciplinary actions. If such an action is taken, the affected health care provider has the right to a full hearing within 90 days of the date of the summary action;
- Incorporates two unanimous recommendations of the Insurance Task Force on Health Care Liability: a) DOHS, county medical associations and CSMS will review all medical malpractice awards (these are public information) and all settlements above a DOHS set threshold to determine whether futher investigation or disciplinary action is warranted; b) the Insurance Commissioner may require all insurance companies writing medical malpractice insurance in this state to submit information, in the aggregate (i.e. preserving the confidentiality of the practioners) to establish a malpractice data base.

Effective Date: July 1, 1986

Signed by Governor: June 5, 1986

Insurance

HB 5400—An Act Concerning Insurance Reform

HB 5400, which was signed by the Governor on May 6, 1986, increases the notice period for non-renewal and for premium charges to policyholders. The non-renewal notice is increased from 60 to 90 days, while the billing notice is increased from 30 days to 45 days prior to the renewal date. The bill raises from $10,000 to $50,000 the annual premium amount below which personal and commercial insurance policyholders are eligible to receive the advance notice of premium billing.

In addition, the bill establishes specific grounds upon which insurers may cancel a commercial risk insurance policy and requires them to give the Insurance Commissioner at least 60 days prior notice of their intention to discontinue offering or reduce writing a line or subline of insurance in the state.

Finally, the bill directs the Joint Standing Committee on Insurance and Real Estate to study, among other things, the process by which insurers establish rates and premiums for liability insurance, evaluation of the claims made policy form, and the establishment of an office of an Insurance Consumer Advocate. The final report is due December 1, 1986.

Effective Date: October 1, 1986, except that the provisions related to cancellation, reduction of coverage, and submission of dates to the Commissioner are effective July 1, 1986

Signed by Governor: May 6, 1986.

SB 157—An Act Concerning Coverage for Home Health Aide Services Under Medicare Supplement Policies

This law requires that insurance policies which supplement Medicare coverage include insurance for home health aide services up to a maximum of $500 per year when: a) the services are provided by a certified home health aide employed by a licensed home health care agency or by a licensed practical nurse, and b) the patient's physician certifies in writing that the services are medically necessary.

This bill also prohibits insurers from charging any deductible or co-insurance costs for these benefits and requires them to include the benefits in Medicare supplement policies issued or renewed in Connecticut on or after October 1, 1986.

Effective Date: October 1, 1986

Signed by Governor: June 5, 1986

SB 360 An Act Concerning Eligibility For Comprehensive Health Care Plan Coverage

Prior law denied comprehensive health care coverage to anyone eligible for Medicare, regardless of age. This act requires insurance companies to offer comprehensive health care plan policies to state residents who are under the age of 65 who are eligible for Medicare as a result of a disability. The bill also changes the type of mental disability a dependent unmarried child must have in order to maintain coverage as a dependent under his parents' policy from *mental retardation* to *mental disability*.

Effective Date: October 1, 1986

Signed by Governor: May 8, 1986

HB 5321 An Act Concerning Availability of Long-Term Care Insurance Policies

This act defines long-term care insurance policies. It also exempts them from the definition for Medicare supplement policies, sets minimum loss ratio requirements for long-term care policies, establishes policy disclosure requirements, and imposes existing loss ratios for individual and group Medicare supplement policies on these policies renewed on or after July 1, 1986. The bill requires the insurance commissioner to adopt regulations to implement the bill's purpose.

Effective Date: July 1, 1986

Signed by Governor: April 28, 1986

HB 5323 An Act Concerning The Primacy of Medicare Benefits Over No-Fault Benefits.

This bill was enacted to bring Connecticut law into compliance with federal law. It repeals provision of Connecticut's No-Fault Motor Vehicle Insurance Law that required: 1) the exhaustion of Medicare benefits before using no-fault benefits to pay an eligible policyholder's accident-related expenses, and 2) a reduction or discount on a Medicare recipient's no-fault insurance premium to reflect the insurer's reduced exposure to loss.

Effective Date: October 1, 1986

Signed by Governor: April 21, 1986

Allied Health Care Practitioners

SB 316 An Act Concerning The Certification of Respiratory Care Practitioners

This law establishes a certification program for respiratory care practitioners administered by the Department of Health Services (DOHS). A certified respiratory care practitioner must practice under *medical supervision* and may not use the title "certified respiratory care practitioner or advertise services using that title unless properly certified with DOHS.

The bill also defines the practice of respiratory care, establishes a procedure for certifying practitioners, and imposes current DOHS disciplinary authority for other professions on respiratory care practitioners violating accepted standards of practice.

Effective Date: October 1, 1986

Signed by Governor: Not signed as of this writing

SB 325 An Act Concerning The Examination for Licensure As A Homeopathic Physician

The bill permits a physician to be examined for licensure as a homeopathic physician, provided that the physician is currently licensed as an allopathic physician or meets the qualifications for licensure as an allopath pursuant to the fifth-pathway program for foreign educated physicians. There currently exists a Homeopathic Licensing Board in Connecticut.

Effective Date: Upon Passage

Signed by Governor: April 28, 1986

SB 97 An Act Concerning The Definition of "Psychological Services" For Licensing Purposes

Psychologists must be licensed by the state before they can perform professional psychological services. Current law defines such services as the application of established principles of learning, motivation, perception, thinking, and emotional relationships to problems of personal evaluation, group relations, and behavior adjustment problems.

SB 97 broadens the definition of psychological services by allowing licensed psychologists to assess, diagnose, prevent, treat, and improve nonphysical psychological disorders or emotional or personality disorders of individuals and groups.

Effective Date: October 1, 1986

Signed by Governor: April 28, 1986

HB 5209 An Act Concerning The Use of Drugs For Diagnostic Purposes By Optometrists

HB 5209 allows optometrists to only use certain drugs for diagnostic purposes and adds a prohibition on acquisition and use of controlled substances. Miotics are removed from the classes of drugs authorized for use by optometrists. Currently, optometrists are prohibited from using drugs except certain devices designated as drugs by the federal government and used for testing and dyes used in fitting contact lenses. Under the bill, recently licensed optometrists can use specified drugs for diagnosis while those licensed more than a year prior to the bill's effective date must complete additional course work approved by the Department of Health Services and pass an exam. Finally, the bill adds ocular pharmacology to the list of areas covered in the optometry licensure exam.

Effective Date: Upon passage

Signed by Governor: April 1, 1986

HB 5217 An Act Concerning Optician and Patients Access to Medical Records

This legislation adds opticians to the list of health care providers who must, upon a patient's request, provide a copy of the patient's medical records. Physicians, osteopaths, chiropractors, natureopaths, podiatrists, physicial therapists, occupational therapists, alcoholism counselors, midwives, nurses, dentists, optometrists, and pharmacists must already supply these records.

The bill further allows health care practitioners to charge a fee of no more than 25¢ per page, plus first class postage, for providing *copies* of medical records to patients. If a physician provides a written summary, he or she may do so at a reasonable charge as under prior law.

Effective Date: October 1, 1986

Signed by Governor: April 28, 1986

Controlled Substances

SB 408 An Act Concerning The Schedule Of Controlled Substances

SB 408 adds a number of drugs to the state's list of Schedule I controlled substances. It also makes dronabinol and alfentanil less restricted by changing their classification from Schedule I to II.

In addition, the Department of Consumer Protection will now schedule drugs by regulation rather than by statute. The Department is required to submit any such changes to the Public Health Committee of the General Assembly on an annual basis.

Effective date: Upon passage

Signed by Governor: May 6, 1986

SB 410 An Act Concerning Controlled Substance Registration

This law excludes physician assistants from those health practitioners who must register with the Department of Consumer Protection before distributing, dispensing, or administering any controlled substance. PA 85-120 which passed last year, gave physician assistants the authority to administer controlled substances under the direction and supervision of a physician. Pharmacies, pharmacists, and nurses are currently excluded from registration.

Effective date: Upon passage

Signed by Governor: May 6, 1986

Anatomical Donations

HB 5756 An Act Concerning Identification of Potential Organ Donors

This statute requires each short-term general hospital, except those for children, to develop a protocol for identifying potential organ and tissue donors. The protocol must contain circumstances under which notification is appropriate and procedures for notifying families of deceased patients and patients whose death is imminent of the donation option. The protocol must be sensitive to family circumstances and take into account the religious beliefs of the patient or family. It must also consider the obvious nonsuitability of the donated organ or tissue.

This bill requires the hospital, in the event of a donation, to contact the appropriate donation procurement agency and cooperate in the donation process.

Effective Date: October 1, 1986

Signed by Governor: May 6, 1986

Legislative Morgue

Each session of the Connecticut General Assembly has its share of bills that are filed for consideration but which fail to be passed into law. Some of these bills never see the light of day. There are numerous bills opposed by CSMS that are now resting in the Legislative Morgue. Below is a brief summary of some of those bills:

SB 321—Would have allowed patients responding to advertisements for free services by physicians, osteopaths, chiropractors, natureopaths and podiatrists to refuse to pay for any *other* services performed as a result of and within 72 hours of answering the advertisement.

HB 5210—Would have required all full-time college and university students under 30 years of age to provide proof of immunization against measles and rubella.

MEDICARE ASSIGNMENT—United Seniors' in Action, a grassroots senior citizens' organization, proposed a measure which would deny licensure to any physician who refused to accept Medicare Assignment. The Medicare Assignment issue was successfully *boxed* (i.e. denied a public hearing) in the Public Health Committee and a motion to add it to the agenda of the Human Services Committee was also defeated.

DRGs FOR HOSPITAL-BASED PHYSICIANS—CHHC submitted a proposal to the Public Health Committee which would have required all pathologists, radiologists and anesthesiologists to accept full Medicare Assignment as well as a salary determined by CHHC. This proposal never appeared on the agenda of the Public Health Committee.

DESIGNATED BLOOD DONATIONS—A bill received a public hearing which would have required hospitals to accept blood donations from a specific individual designated for receipt by a particular patient. Through discussions with the Red Cross, Connecticut Hospital Association and the proponents of the bill, a compromise was reached and the bill was dropped.

CERTIFICATION OF ACUPUNCTURE THERAPISTS—the bill passed both houses of the legislature, but was vetoed by the Governor at the request of CSMS and numerous other Associations. The act would have permitted an acupuncture therapist to be certified by the Department of Health Services (DOHS). A certified acupuncture therapist would have had the choice of working under the general supervision of a physician, osteopath, chiropractor, or natureopath. In addition, the bill would have permitted osteopaths, chiropractors, natureopaths and podiatrists to practice acupuncture therapy without obtaining certification from DOHS.

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Report of Panel on Lasers in Medicine and Surgery

AMA COUNCIL ON SCIENTIFIC AFFAIRS

(Second of Two Parts)

Lasers are in routine clinical use in many medical and surgical specialties, and a variety of new uses are under investigation. The Panel on Lasers in Medicine and Surgery has prepared a two-part report: Part I was a review of the biophysics, safety-in-use and federal regulation of lasers used in medicine and surgery; clinical applications of lasers are summarized in Part II.

Clinical Applications

Ophthalmology

Working with lasers for more than two decades, almost from the initial introduction of the instrument in 1960, ophthalmologic investigators and clinicians have developed surgical and diagnostic uses for a wide range of laser-tissue interactions. The most widely used lasers in current ophthalmologic practice are the argon-ion, Q-switched Nd:YAG and krypton-ion (Table 1, printed in Part I), and some anterior segment applications for the CO_2. Investigations are in progress with the organic dye laser for photo-coagulation and photoradiation, and the excimer and TEA CO_2 lasers for use in keratorefractive surgery.

Surgical applications use thermal, photochemical or ionizing laser-tissue interactions (Table 2, printed in Part I).

Photocoagulation is used in surgical management of proliferative diabetic retinopathy, choroidal neovascularization in aging-related maculopathy, retinal breaks, angle-closure glaucoma and open-angle glaucoma. Photocoagulation also is used for goniophotocoagulation (of neovascularization) and photomydriasis, the management of central serous retinopathy, retinal macroaneurysms, branch retinal vein occlusion, diabetic macular edema and retinal or choroidal tumors.

Photovaporization is used in surgical management of ciliary body tumors and neovascular glaucoma, and in oculoplastic surgery. Intraocular applications of the CO_2 laser to sever and cauterize fibrovascular structures without traction await more effective intraocular delivery systems.

Photochemical effects of the laser are under clinical or laboratory investigation as ophthalmologic surgical procedures: photodynamic therapy in treatment of choroidal melanomas, and photoablation for making corneal incisions of precise width and depth.

Photodisruption is used to make a sterile intraocular incision in a posterior capsule that has opacified after extracapsular cataract surgery, for iridotomy and for incision of vitreous structures in the anterior or posterior segment. Potential uses of photodisruption include reopening of closed filtering blebs, treatment of aphakic and pseudophakic pupillary block, sphincterotomy, and repositioning of pupillary-captured intraocular lenses.

Diagnostic applications include:

- Retinal interferometry, in which a helium-neon laser beam is divided and component beams are introduced into the eye so as to form high-contrast interference fringes on the retina; the finest fringe pattern that a patient can identify is a measure of retinal acuity.
- Scanning laser ophthalmoscopy, in which a scanning laser beam is used to illuminate a patient's retina; laser light scattered out of the eye from each point in the raster formed by the scanning laser beam is collected and displayed on a video screen, providing a real-time video image of the patient's fundus for determination of the exact retinal origin of a visual defect.
- Laser Doppler velocimetry, in which helium-neon laser light that is scattered off a moving column of red blood cells in a retinal vessel is monitored with one or more light detectors; the shift in wavelength of collected light relative to incident light provides a noninvasive measure of the velocity of blood flow in a retinal vessel.
- Focal electroretinography, in which a helium-neon laser beam is used to stimulate a localized area of the retina such as the macula; monitoring of the resultant electroretinographic response provides documentation of localized functional retinal abnormalities that may not be apparent by other diagnostic means.

Dermatology and Plastic Surgery

Practitioners in these quite distinct specialties share many interests and approaches in clinical use of lasers.

The CO_2 and the argon lasers are the instruments most often used. Results tend to be most satisfactory at body sites, such as the face, noted for uncomplicated and rapid wound healing.

Because the argon laser wavelengths are absorbed well by hemoglobin, it has some degree of specificity in its effect upon vascular lesions. Table 3, printed in Part I, lists lesions that may respond to argon laser therapy.

The argon laser is treatment of choice for port wine stain (PWS) and is the first PWS treatment effective in a majority of patients. Most PWS patients treated with the argon laser have a favorable result defined by lightening without scarring, particularly if the lesion was intensely deep red to purple. Risk of scarring is a contraindication in children under 12 years of age, especially those with flat, pink PWS on their faces.

The CO_2 laser used for incision and simultaneous cauterization has been applied successfully in excising vascular tumors, lesions in vascular areas, in patients with hypertension and patients receiving anticoagulant therapy, in Mohs chemosurgery and in removing keloids by shave excision. Used for tissue vaporization, the CO_2 laser accomplishes tattoo removal and is treatment of choice for therapy of large, recalcitrant condyloma acuminata and warts. It has been used to treat skin cancers, miscellaneous superficial lesions, and may be quite effective in treatment of PWS and other vascular lesions initially treated only with the argon laser. The combination of excision and vaporization may be used in treatment of rhinophyma.

Tunable dye lasers have been used successfully in research and in early clinical trials in treatment of vascular lesions, with much greater specificity of damage to blood vessels, with sparing of adjacent tissue elements.

Cardiovascular Applications

Investigation of potential laser applications is being pursued at several centers, but procedures are still experimental. Laser angioplasty appears to offer great promise as an eventual clinical application.

A laser beam delivered through optical fibers can vaporize and debulk atherosclerotic plaque in situ, even in totally occluded vessels or deep in small arteries. The technique is believed to have great significance for a growing population of patients who have undergone coronary artery bypass procedures, but who will need further revascularization within 10 to 15 years. Many of these patients will be poor candidates for repeat surgery or balloon angioplasty because of diffuse vessel disease, multiple previous surgical procedures, or precluding medical conditions.

Early results from patient trials have shown successful laser angioplasty. Questions to be resolved include the duration of patency established by laser recanalization, the nature and amount of debris formed by plaque vaporization, and how well healing takes place in the laser-treated arterial wall. The most important outstanding question is how to prevent laser-beam perforation of the vascular wall.

Other future laser applications may include:

- Adaption of photodynamic techniques to recanalization, localizing photosensitizers in plaque to enhance vaporization.
- Photoablation of abnormal conduction tissue in the heart to control certain types of tachycardia. Experiments on the His bundle in dogs have resulted in complete heart block.
- Valvuloplasty in elderly patients with severe heart failure who cannot tolerate valve replacement surgery.
- Creation of artrial septostomy in congenital heart disease.
- Vascular bonding in lieu of suturing for better long-term patency in small vessels.
- Myectomy of the hypertrophic septum in obstructive cardiomyopathy, a procedure reported done in one patient.
- Direct muscular revascularization, a controversial possibility.

Gastrointestinal Surgery

Endoscopic approaches make the gastrointestinal tract a site of rapidly increasing laser application. Optical fibers have been developed which fit through the open channel of most gastroscopes and colonoscopes. Surgical endoscopic applications include control of bleeding, coagulation of nonbleeding vascular lesions, removal of benign and malignant mucosal lesions, and various incisional uses.

Argon and Nd:YAG lasers are used to control gastrointestinal bleeding from a variety of lesions that include varices, Mallory-Weiss tears, peptic ulcers, multiple erosions and telangiectasia. Endoscopic laser control of gastrointestinal bleeding has special application in patients with massive bleeding, who likely will not cease bleeding spontaneously, who are at high risk because of cardiac, pulmonary, renal or other complications.

The laser is used extensively in treatment of nonbleeding, hereditary or nonhereditary, vascular lesions of the gastrointestinal mucosa. Lesions may be single, multiple, small, punctate or large and plexiform. The most frequently treated are found in Osler-Weber-Rendu disease.

Very larger arterial malformations which are visualized on angiography and have a large intramural or serosal component cannot be managed by laser therapy.

The argon laser is used through a flexible sigmoidoscope to remove polyps in the rectal remnant following abdominal colectomy in patients with Gardner's syndrome. The procedure is feasible in patients with multiple, small, sessile colonic polyps.

Laser therapy of malignant gastrointestinal mucosal lesions is largely for control of bleeding or palliation.

Several reports detail control of bleeding from cancer of the esophagus, stomach, duodenum and colon. Bleeding control is useful in allowing preparation of the patient for definitive surgery. In other instances laser intervention obviated surgery by effecting hemostasis in incurable lesions.

General Surgery

Physicians employing open operative techniques make less use of lasers than their endoscopically oriented colleagues. The laser may seem less useful to the general surgeon than to those who have to work in small, inaccessible areas.

The CO_2 laser is the general surgeon's instrument of choice for incision and excision by vaporization.

In excision of decubitus ulcers using the CO_2 laser, the incidence of wound infection is reduced and better primary healing is induced.

In removal of leukoplakia and premalignant lesions of the oral cavity, the laser vaporizes involved mucosa identified by staining. Postoperative wound healing is somewhat slow but postoperative biopsies indicate good removal of the lesions.

Patients with blood clotting problems may be helped by use of the laser when undergoing surgical procedures. The CO_2 laser has been used successfully in patients undergoing anticoagulant therapy and in thrombocytopenic purpura and in abdominal surgery patients with hemophilia. Laser hemostasis is less effective in patients with a platelet count of less than 25,000.

The laser has been employed widely for palliative excision of far advanced malignancies of the thoracic and abdominal wall, suggesting increased capability for management of large, previously inoperable lesions. The extremely painful nodular, protruding peritoneal recurrences of carcinoma of the rectum following abdominal perineal resection have been vaporized by the CO_2 laser with good results.

Laser sealing of lymphatics and reduction of bacterial or tumor spread is controversial.

Gynecology

The largest surgical use of lasers is currently in gynecology, as indicated by data from laser manufacturers. A brief report provides only an overview of a large and fast-developing area.

The CO_2 laser is the principal instrument used in gynecology. Cervical intraepithelial neoplasia is treated by vaporization to a depth of 7 mm., thereby eliminating the disease not only from the surface epithelium but also from 99.7% of possibly involved endocervical glands. As an office or outpatient technique it can be performed under local anesthesia or without anesthesia. The procedure takes approximately five minutes, is virtually bloodless, and is without significant side effects.

Laser excisional cone substitutes the laser for the cold knife under selective circumstances. A hospital outpatient setting is preferred. Healing occurs rapidly without stenosis or scar formation.

Laser combination conization is a new procedure, for use when intraepithelial neoplasia extensively involves the ectocervix and extends into the canal. Classic, sharp, or laser excisional cone would virtually remove the entire cervix and lead to infertility. Vaporization alone cannot be done because the lesion extends beyond the view of the operator into the endocervical canal. The laser combination cone combines a narrow excisional cone with peripheral vaporization. Sparing of tissue is the major advantage.

Vaginal and vulvar intraepithelial neoplasia are both treated effectively by vaporization. The laser procedure is bloodless and does not require skin grafting. Virtually no scarring occurs.

Condyloma acuminata is very effectively treated by vaporization. The laser has the ability to reach otherwise inaccessible lesions and the heat of the laser beam eliminates the virus.

Intra-abdominal applications are appearing. Hand-held lasers are used to uncap endometriomas of the ovaries. The interior of the cyst is then vaporized allowing the ovary to be preserved. Endometriotic foci may be precisely vaporized using lower irradiance microscopically. Small adhesions covering the ovary or between the ovary and tube can be accurately and bloodlessly vaporized by the microscopically directed laser. The laser also is useful for performing cornual shaving procedures, myomectomy, and metroplasty. The most recent application, laparoscopy, can be used to treat endometriosis and for the lysis of fine adhesions.

Neurosurgery

The carbon dioxide laser also is the mainstay of laser neurosurgery. The thermal lesion produced by the CO_2 beam on cerebral and spinal tissue is more contained and less associated with surrounding edema and abnormal electrical activity than the most precise conventional instrument available. Consequently, the CO_2 laser, used free hand or coupled to the operating microscope, has become the benchmark against which other wavelengths are compared.

In neurosurgery, aside from the precision offered by the highly focused laser beam, the ability to incise or remove tissue immediately adjacent to sensitive, frequently compromised, neural and vascular structures remains the most important use of the instrument. Limits of operability for benign tumors have been extended through the knowledge that even the most sensitive areas of the neuroaxis can be decompressed by tumor vaporization without the significant additional compromise seen with standard operative technique.

Because malignant tumor processes extend along normal fiber tracts to varying distances from the main mass, laser vaporization offers no advantage in terms of cure or prolongation of life. On the other hand, the ability to gently remove malignant tissue even deep within the central structures using a laser coupled with computer-assisted sterotactic devices has allowed a greater reduction of tumor burden in these areas than was heretofore available.

Lasers make possible selective ablation of neural tissue to effect a physiologic change without adversely affecting surrounding structures. The creation of dorsal root entry zone lesions to control intractable pain, the performance of midline myelotomy for spasticity, and the severance of the lateral spino thalamic tract for uncontrollable contralateral pain are notable.

Although lasers have been claimed to reduce scar formation in disk surgery and neuroma formation at the end of severed nerves, substantiation is lacking. The use of a laser in disk surgery is advantageous only as it reduces visual impediment in "minimal exposure" approaches such as the "microdiscectomy."

Recently, Nd:YAG lasers have achieved greater popularily in American neurosurgery, directed mainly toward surgery for arteriovenous malformation of the brain and highly vascular tumors of the brain and spinal cord. The ability to transmit Nd:YAG energy through an optical fiber, and its penetrance through clear fluid media, indicate that this will be an important wavelength in endoscopic neurosurgery and intraventricular neurosurgery.

Tissue bonding interest is centered around the use of milliwatt CO_2 systems. Microvessel anastomoses, nerve anastomoses, dural approximation, and the joining of various hollow viscera have been successfully performed, reducing operative time and reducing the need for microsuture. Vessels joined in this manner have been shown to grow and expand normally, free from granuloma formation secondary to the foreign body of the suture material.

Intravascular navigation and canalization, or removal of plaque by vaporization or biochemical disintegration has been performed in experimental systems with a variety of wavelengths from the infrared to the ultraviolet. Further developments will be of major import in the treatment of occlusive cerebrovascular disease. Biostimulation, for neural regeneration and/or treatment of pain, has received much press but little scientific validation. Well-controlled, scientific studies are currently underway.

Otolaryngology-Head and Neck Surgery

Four types of lasers are currently in use in otolaryngology-head and neck surgery: argon, argon tunable dye, Nd:YAG, and CO_2. Of these, the CO_2 has been used the longest and its applications most accepted. Argon has been used in management of otosclerosis, in rhinology in treatment of patients with hereditary telangiectasia, and in facial plastic surgery for cutaneous vascular lesions. The argon tunable dye laser used in conjunction with hematoporphyrin derivative is being seriously investigated and is undergoing trials for use in diagnosis and management of squamous-cell carcinoma of the head and neck. The Nd:YAG laser has been accepted as an effective tool in management of patients with obstructing tracheobronchial neoplasm

Macroscopic applications of the CO_2 laser in the oral cavity include: excision or ablation of benign tumors; one-stage tongue release; excision or ablation of multiple area of leukoplakia; excision of some superficial carcinomas and debulking of large recurrent or inoperable tumors for palliation.

Within the nasal cavities and paranasal sinuses, the CO_2 laser is used to treat choanal atresia, hypertrophic inferior turbinates, squamous papilloma, recurrent inverted papilloma, and hereditary hemorrhagic telangiectasia. The argon laser may be more efficacious in the latter condition.

Tonsillectomy, excision of tonsillar neoplasms, and excision of neoplasms of the posterior pharyngeal wall also can be performed with the laser. Peritubal adenoid tissue and recurrent papilloma in the nasopharynx can be ablated by reflecting the radiant energy of the CO_2 laser off a front surface or stainless steel mirror.

Microscopic applications of the CO_2 laser include:

- Surgery for recurrent respiratory papillomatosis, while not curative preserves normal laryngeal structures and maintains the translaryngeal airway.
- Surgery in the child for webs, subglottic stenosis, capillary hemangiomas and other lesions also preserves normal tissue and reduces postoperative edema.
- Surgery in adults for polyps, nodules, leukoplakia, papilloma, cysts and other benign laryngeal conditions with maximum preservation of normal tissue.
- Incision of webs and subglottic stenoses; anterior commissure webs tend to recur less after laser resection. Stenoses should not be treated by laser if skeletal support is needed as the laser will not provide this.
- Endoscopic arytenoidectomy allows the surgeon to precisely vaporize the mucosa and underlying arytenoid cartilage layer by layer in a dry field; this facilitates the restoration of a competent airway without sacrifice of an intelligible voice.

Endoscopic transoral treatment of squamous cell carcinoma of the larynx with the CO_2 laser offers advantages of precision, hemostasis and decreased postoperative edema. The laser makes it possible to remove bulky tumors of the anterior commissure area or vocal fold to obtain an accurate assessment of their extent for purposes of staging and treatment.

Use of the CO_2 laser coupled to a ventilating bronchoscope allows the surgeon to perform hands-off endoscopic surgery through the relatively long and narrow operative field. Indications for bronchoscopic laser surgery include management of recurrent respiratory papillomatosis or granulation tissue involving the trachea, and resection of selected areas of tracheal stenosis. Tracheal and proximal endobronchial adenomas and webs also can be resected. The laser bronchoscope can reestablish airway in patients with selected obstructing tracheal and proximal endobronchial malignancies. The major contraindication to use of the laser bronchoscope is extraluminal compression of the trachea by an extrinsic tumor.

Urology

The endoscopic expertise of urologic surgeons and the easy adaptation of laser energy to standard cystoscopes facilitated the use of lasers in urologic surgery.

The application of lasers as definitive therapy for various lesions of the external genitalia include: treatment of condyloma acuminata with either a CO_2 or Nd:YAG laser; ablation of erythroplasia of Queyrat (carcinoma in situ) of the glans penis with CO_2 and Nd:YAG laser; ablation of selected invasive squamous cell carcinomas of the penis with the Nd:YAG laser.

Laser treatment of urethral strictures has been disappointing, giving short-term improvement but recurrence of the majority of strictures in three to six months.

Laser treatment of transitional cell carcinoma of the bladder may be superior to electrocautery resection. Since laser treatment coagulates tumor without direct contact, the recurrence rate of papillary bladder tumors due to implantation may be decreased. Controlled studies to verify the presumption have not been completed. Treatment is accomplished without anesthesia in an ambulatory outpatient setting. In general, no bleeding occurs and postoperative Foley catheter drainage of the bladder is unnecessary. Obturator nerve stimulation is avoided.

Clinical trials of laser treatment of invasive bladder cancer has been restricted to patients who are not candidates for cystectomy or those who refuse surgery. The majority of patients with superficial muscle invasion have had normal post-treatment biopsies. Lasers generally have been ineffective as definitive therapy for bulky tumors or those with invasion beyond the bladder wall.

Rigid instruments recently developed allow endoscopic examination of the entire ureter and upper urinary collecting system. A flexible Nd:YAG or argon laser fiber can be inserted through the working channels of the instruments, opening the possibility of endoscopic treatment of certain papillary tumors of the ureter or renal pelvis. Early clinical experience has shown the technique effective in properly selected patients with small papillary tumors.

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Law and Medicine in Confrontation

A Dean's Dialogue

Deans Leon E. Rosenberg of the School of Medicine and Guido Calabresi of the Law School spoke to standing room only audiences as they discussed such medicolegal issues as malpractice law, bioethics and third party payors in a two-part series billed as "A Deans' Dialogue: Law and Medicine in Confrontation." On December 2, Dean Rosenberg addressed medical and law students and faculty in the Law School Auditorium; and on the following Monday, Dean Calabresi spoke before a similar audience in the medical school's Harkness Auditorium. Each dean responded to the other's remarks following the talks.

Dean Rosenberg set the tone of the dialogue when he expressed deep concern about the future of the medical profession, predicated on the "pervasive, unwelcome, crushing embrace of medicine by law.

"Every participant in the health care system—doctors, nurses, hospital administrators, paramedical personnel—is beset by an onslaught of new laws and regulations affecting every phase of medicine—from care of the critically ill newborn to that of the terminally ill aged; from the decision to terminate a pregnancy to that concerned with termination of life-support systems; from criteria for hospital admission to those involved with Medicare reimbursement; from 'Baby Doe' regulations to 'squeal' laws," he said.

"And worst of all, because it is the most personal, physicians are forced to live with the spector of malpractice litigation constantly in their minds' eye. This legal assault has occurred so swiftly and has been implemented so harshly that it has begun to erase some of the very attractions long associated with pursuing a medical career—autonomy, independence, approbation, inquiry," Dean Rosenberg added.

"The issue, in my view, is not whether law has a legitimate claim to a greater scrutiny of and control over medicine, for clearly it does. Rather, the question is whether the legal means being used to control medicine and the conduct of some of the lawyers implementing the laws are moving our society in a direction such that the largest number of people have available the highest quality health care," he said. "Sadly, my answer to this question is'NO'".

Dean Rosenberg cited two examples to support this response. The first had to do with attempts to decrease the enormous cost of hospitalizing patients, such as the Diagnostic Related Group system of hospital reimbursement and other strategies which are aimed at keeping people out of the hospital who don't need to be there, such as the recently implemented program of the federal Health Care Financing Administration (HCFA) which manages Medicare regulations.

This program mandates that all Medicare patients scheduled for elective surgery or emergency admission to any hospital in Connecticut will be required to have preadmission screening and certification from the state's HCFA delegate—the Connecticut Peer Review Organization (CPRO). If the admitting physician fails to comply, either by not seeking certification or by admitting the patient despite denial of the request for certification by the CPRO, neither the hospital nor the physician will receive reimbursement from Medicare. Private insurance carriers, according to the dean, are establishing similar preadmission approval systems with perhaps even tighter controls.

"The message is clear," he said. "In the name of cost containment, it has been determined that the judgment of CPRO or insurance company personnel based on no patient contact is superior to that of the physician caring for the patient . . . This is health care by a bureaucracy out of contact with the patient and out of touch with the physician. It tends to mock the age-old ethical precepts that each patient is unique, that the physician's first obligation is to his or her patient, and that clinical skill, knowledge and judgment are gained by experience. How can the many subtle determinants leading to the decision to hospitalize an elderly person be reduced to the simplicity of 'yes/no' certification by telephone? Who will be held culpable if a patient deemed uncertifiable for admission dies at home for want of hospital attention? When does the life of one person count for more than the dollars of many?" he asked.

The other issue is medical malpractice litigation—an incendiary topic that is front page news.

"Professional rivalry between physicians and lawyers is understandable, perhaps inevitable. The hostility, misunderstanding, and antagonism which now characterize the dialogue between members of the two disciplines in the area of malpractice, however, has reached unacceptable proportions. It poses a threat to the two warring professions who may soon hear from the public something like 'a pox on both your houses.' More importantly, it places at risk the very quality of health care physicians are committed to provide and lawyers are bound to protect. If, for example, a significant fraction of obstetricians stop delivering babies and young M.D.'s

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follow suit by going into other less litigation-liable specialties, then one day maternal and infant mortality rates will begin to climb. Clearly, wisdom dictates changing course before such dire consequences occur," advised Dean Rosenberg.

To underscore the magnitude of the malpractice crisis, Dean Rosenberg cited a few statistics including that fact that in 1983, one of every five practicing physicians in the United States was sued for malpractice with a total of 42,000 malpractice claims lodged in that one year; for all physicians, premiums for malpractice insurance increased by 238 percent between 1975 and 1984 and in that same interval, mean physician income increased by 92 percent; in 1975, the average malpractice judgment was $95,000 and in 1984, it was $338,000, and in 1984, the national cost for the practice of "defensive medicine" was estimated at $15 billion.

The legal definition of medical malpractice is straightforward and originated under the law of torts, noted Dean Rosenberg. According to the law, once a physician-patient relationship has been established, the physician is obligated to diagnose and treat that patient with "due care". Failure to do so constitutes negligence for which the injured patient may sue and recover monetary damages.

"It is this claim of negligence which lies at the heart of the medical malpractice problem," he contended. "All physicians know that medicine is an imperfect science, that maloccurrences take place, and that some maloccurrences result from negligence and incompetence."

"The issue, in my view, is not whether law has a legitimate claim to a greater scrutiny of and control over medicine, for clearly it does. Rather, the question is whether the legal means being used to control medicine and the conduct of some of the lawyers implementing the laws are moving our society in a direction such that the largest number of people have available the highest quality of health care." — Dean Rosenberg

As to why the issue of medical malpractice is so explosive, Dean Rosenberg maintains this is largely a function of the vast ignorance of physicians about law, and the equally cavernous ignorance of lawyers about medicine. "If physicians understood that the law doesn't believe in absolute truth but rather employs an adversary system to resolve conflicts by coming as close to the truth as possible, they might not see a claim of professional negligence as such a mortal threat to their self esteem.

"If lawyers understood that medicine has no adversary other than illness, injury, or death and that the practice of medicine depends on the willingness of patients to believe in their physician's expertise, they might understand why a charge of professional negligence tends to undermine the very authority and trust so crucial to the doctor-patient relationship," he said. "Because the vast majority of law students are not required to take a course in 'biomedical law' and most medical students learn little if any 'legal medicine', both groups are socialized into their respective professions without any positive endorsement of the other. Thus, the bright, aggressive, ambitious people who become our doctors and lawyers substitute professional chauvinism for mutual understanding and learn only too well how to use words like 'shyster', 'quack', 'ambulance chaser' or 'butcher'.

". . . This legal assault has occurred so swiftly and has been implemented so harshly that it has begun to erase some of the very attractions long associated with pursuing a medical career — autonomy, independence, approbation, inquiry."

— Dean Rosenberg

"Can it surprise us then, that when members of these two professions, who have had so little contact with each other during their formative years, confront each other in the charged, complex and visible cauldron of medical malpractice litigation, that physicians scream that our society must do something to keep rapacious lawyers from destroying our system of health care, and lawyers yell back that society must do something to keep incompetent doctors from killing and maiming people?"

Since what we as a society are doing about medical malpractice obviously isn't working, we must do something else, according to the medical school dean. First and foremost, we must begin to educate the public to the fact that medical care can sometimes be "hazardous to your health" and that "physicians cannot always solve patients' problems and may even make them worse; that there are inherent contradictions in the demands for medical care of high quality and equally affordable cost; and that this country has among the best health care systems in the world because the great majority of its practicing physicians are well trained, skillful and caring."

Lawyers, he said, must learn that there is a real and critical difference between maloccurrence and malpractice; that physicians speak truthfully when they say that being sued for malpractice is among the most devastating and disfiguring catastrophies that can happen to them, and that demanding a standard of professional responsibility from physicians more rigorous than that expected for themselves is the ultimate hypocrisy.

In turn, the dean said that physicians must learn that the venerable contract between doctor and patient must be rewritten so that the physician is viewed as a partner in the transaction rather than as an infallible, unchallengable authority, and that "failure to discipline and weed out incompetent or impaired physicians has so eroded the public's confidence that they, the patients, not we, the doctors, are the primary focus of our ethical concerns; and that the single most effective safeguard against malpractice suits is the bond established between doctor and patient through informed consent and thoughtful communication."

This educational agenda is long and challenging. It will be achieved only if it is addressed in the classrooms of our medical and law schools, in the workrooms of our news media, in the board rooms of our insurance companies, and in the living room of our citizens. While all this is going on, I believe we must modify—perhaps even overhaul—the legal system which adjudicates professional liability claims. . . .

"Broader reform measures, aimed at lawyers and physicians, must be considered to put some limit on damages for pain and suffering, to subject contingency fees to a sliding scale by which the attorney for the plaintiff's fraction of monetary damages falls as the size of the judgment rises; to require periodic rather than lump sum payments for large awards; to mandate risk-management programs for physicians and hospitals; to insist that insurance companies make data concerning malpractice awards available to state agencies responsible for disciplining physicians, and to fund expanded state disciplinary agencies by increasing fees for licensure from physicians and allocating the additional revenue to the disciplinary authority. Such reforms will not do away with medical injury, negligence or incompetence. They will, however, demonstrate to physicians and lawyers alike that the threat to the public's health posed by the current malpractice litigation nightmare must be contained until something better comes along," predicted the dean.

The way out of the malpractice dilemma, he contends, is through educating the public as well as physicians and lawyers, and by modifying the legal system which adjudicates professional liability claims. A possible solution, he suggested, would be a "no-fault"-based national compensation system for medical injury along the general lines of workmen's compensation or automobile accident liability.

"One of the troubling things about the whole discussion of malpractice is how often doctors on the one side and lawyers on the other, seem to be primarily concerned with what malpractice law means for them rather than what it means for patients."
— Dean Calabresi

In conclusion he said, "The constraints, contradictions, and contumely currently being heaped on physicians are not justified by any errors physicians have committed in meeting their professional and social responsibilities. The medical profession must be given back a central role in the development of national health care strategies because it is among the few groups with the expertise to help make some of the difficult choices which lie ahead. The public, through the law, and lawyers, through their professional behavior, must show restraint in the demands they make of Medicine because, in the final analysis, the public stands to lose the most if the profession of Medicine is diminished and, by being diminished, attracts to its ranks a less capable and dedicated breed of physician. Surely, that is not the way to ensure one of our citizens' unalienable rights—to life."

In his talk on December 9, Dean Calabresi responded, "One of the troubling things about the whole discussion of malpractice is how often doctors on the one side and lawyers on the other, seem to be primarily concerned with what malpractice law means for them rather than what it means for patients." Malpractice law fails to induce better medical care and to efficiently compensate patients who suffer severe medical ill effects, because instead it produces "outrageously wasteful defensive medicine," observed the Law School dean, whose father and brother are physicians.

Why do we stay with malpractice? Because other methods of inducing better medical care are equally flawed, according to Dean Calabresi.

In response to Dean Rosenberg's proposal for implementation of a no-fault-based national compensation system, the law school dean advised, "We still can, and should, decide what medical maloccurrences are sufficiently dire to justify such a compensation system. There may be differences on this question, but however resolved the cost of the approach is likely to be small compared to the disaster of our current malpractice law. To do it today, however, we would have to make such a fund take the place of the malpractice suit, for we cannot roll things back and return to the pious fraud malpractice was," he said. "We have all eaten the fruit of the Tree of Knowledge and can no longer successfully pretend that we are seeking medical perfection through a do-nothing malpractice law, while compensating injured parties through another system . . . .

"We can only get out of our mess by admitting what is hard to admit, that lots of errors and maloccurrences will occur, that as to all but the grossest (which self-regulation or patient choice may control), there isn't anything we can do, and that the best we *can* do is alleviate the suffering of those most severely injured."

Leaving the subject of malpractice, he turned to two areas that concern him about how physicians behave today, both involving failure on the part of physicians to take responsibility. "They both will lead, are leading, to precisely the kind of crushing embrace of medicine by law that Dean Rosenberg suggested was disastrous," he cautioned.

The first is the area of payments and insurance for medical care, which he contends is not viewed by most doctors as something they should become involved in, except when "somehow the insurance system ends up asking them to fill out outrageous forms or paying them less than they think they should get." And yet, he believes, it is one of the factors that most destroys a decent patient-physician relationship.

"How can a patient believe that a doctor or hospital cares for her or his well being when entrance to a hospital or to a doctor's office—often however dire the emergency—

awaits proof of insurance or other form of capacity to pay? How can the patient believe the doctor cares, when after treatment or discharge, in many, many cases the patient is left unaided to fill out forms that—believe me—strain the capacity of highly trained lawyers or accountants?", asked Dean Calabresi.

"How can any semblance of relationship persist when after the 'third-party-carrier' has inevitably returned the forms as inadequately filled, or sent to the wrong carrier, or with a reimbursement that bears no relationship to the doctor's or hospital's bill, the patient is faced by a dunning letter from doctor or hospital threatening interest or far worse penalties, if no payment is made at once?" he asked.

"It is there that I and many lawyers would find the medical profession wanting," he said.

"Why are doctors and their associations not lobbying, shouting, writing letters, and as important, joining lawyers in drafting bills to create a system of health care insurance that is speedy, efficient, and easily understood by the ordinary patient?"

When he raises this question with doctors as well as with lawyers, Dean Calabresi said, he is usually told that there isn't time for such lobbying and thinking and bill writing. "But there is time (on both sides) to lobby and fuss about malpractice. . . No, it is not a matter of time, but a matter of interest, of caring."

The second issue of physician responsibility is harder and more deeply important in that it deals with doctors being willing to take responsibility for desperately ill patients. "There are, I think, few things more scandalous than doctors who, when a patient and that patient's family have said that extraordinary medical treatment should be avoided, nevertheless insist on such treatment, or worse, ask that a court decide for them whether treatment must take place, or whether the plug should be pulled."

"In the past, doctors made analogous decisions routinely, and admittedly were criticized for being high-handed and not communicating with patient and family," said Dean Calabresi. "They were told they were playing God and shouldn't. There is plenty of room, however, between playing God and trying to duck the responsibility that being a member of a profession has to entail. It is for being unwilling to act in this middle zone of uncertainty that doctors have been most severely criticized by legal scholars.

"Why are doctors and their associations not lobbying, shouting, writing letters, and as important, joining lawyers in drafting bills to create a system of health care insurance that is speedy, efficient, and easily understood by the ordinary patient?" — Dean Calabresi

"Here, as in so many things between law and medicine, there is a fundamental lack of understanding by each profession of what the other is about," he pointed out. "The doctor who seeks legal assurance that a tragic choice should be made in one way (while keeping the patient and family in limbo), believes that the law is set of clear rules that can give 'yes' and 'no' answers to conduct, and can do it publicly. The law knows that this cannot be so, that often the law will declare one thing and permit the opposite precisely because it is the only way to allow a society to cleave to conflicting ideals," he added, citing an example of euthanasia to explain his point.

"When a doctor invokes the law in such a situation, that doctor not only fails to give the patient and family the care they have a right to—which means immediate care—but also starts a process that goes a long way toward establishing the crushing embrace the doctor will later, properly, complain about," said Dean Calabresi. ". . .to people outside of medicine, a doctor's role is *not* just to keep people alive at all costs; it is to care for them, to treat them according to their best interest. That, as I said earlier, involves a decent medical payment system, but it also involves allowing people to die with dignity and without having to go to court to do so. . ."

". . . a doctor's role is not *just to keep people alive at all costs, it is to care for them, to treat them according to their best interest. That involves a decent medical payment system, but it also involves allowing people to die with dignity and without having to go to court to do so. . ."*— Dean Calabresi

Dean Calabresi noted that one person's death with dignity is another person's premature abandonment, which is just one reason why *yes* or *no* legal rules won't work. "It requires exquisite sensitivity to the particular situation of the particular patient and that patient's family," he explained.

. . ."Most doctors fear the crushing embrace of the law. Most thoughtful lawyers fear being called in to regulate medicine. They fear the same embrace just as strongly," he said in conclusion. "If the embrace comes, then, it is because the professions have not worked together to find ways of accomplishing what the public desires of us. There are things the public wants that cannot be given to it—perfection in medicine and simple rules in law.

"But there are things the public wants that can be given it—the capacity to cope financially with catastrophic medical maloccurrences, the possibility of having decent medical care without being badgered by bureaucrats armed with unintelligible financial forms and requirements before and after treatment, and the chance to live without the fear of either being discarded prematurely or being kept alive in intolerable conditions. If lawyers and doctors, both, focus more on these things that the public wants from us in our interactions, and less on what benefits *us* or frightens *us* most in those interactions, we will be able to respond to the public, be true to our calling, and, in the long run, also remain the professions we would wish to be."

Women and Organized Medicine

CLAIR M. CALLAN, M.D.

Women members must be urged to accept committee appointments, must be encouraged to accept leadership roles and must be consciously supported if they choose to run for elected office.

The number of women physicians is increasing every year and will continue to do so. Although their number is growing, their visibility is not. This is particularly evident in the ranks of organized medicine and is causing concern among its leadership.

Women in Medicine Project

Several years ago the American Medical Association (AMA) established an Ad Hoc Committee on Women Physicians in order to examine the problems and barriers experienced by women physicians that keep them from playing an active role in organized medicine. One of the Committee's products was the development and publication of a policy on maternity leave for residents. It also identified the need for a continued effort directed to encouraging women physicians to take a more active role in organized medicine.

The AMA decided to continue the thrust of the committee by establishing the Women in Medicine Project—an ongoing effort to provide direction and coordination for AMA activities involving women physicians. The projects primary objective is to gain access for women physicians into the mainstream of organized medicine. The advisory panel for the project has concluded that women will be "fully mainstreamed" when the proportion of female physicians joining the AMA reaches the same level as the proportion of male physicians joining, and when the number of women in AMA leadership positions reaches a level proportional to their numbers in organized medicine.

Despite this commitment to women physicians within the AMA, there has been little progress during the last 12 months. While this has been a period when women are clearly becoming more visible among the ranks of practicing physicians, there has failed to be a corresponding increase in activity of women physicians in organized medicine. In 1984, five women were delegates and 15 were alternates in the 357-seat House of Delegates, and eight women were members of one of the AMA councils. In 1985, in the 371-person House, there were five women as delegates, and 18 women as alternates, and the number of women with council seats was down to six.

Reasons for Not Participating

Why aren't women making a more significant impact on the world of organized medicine? There are several possible reasons.

Dual roles. Women physicians still assume the major responsibility for the care of home and children, just as working women do who are not physicians. Such responsibilities leave very little time to become involved in what they may perceive as non-essential activities.

There are very few women physicians who hold a position of power and influence in medical politics.

Lack of role models. The number of women physicians who hold a position of power and influence in medical politics is very small. This is true at all levels—committee positions, elected positions and senior staff positions. Lacking role models, women may fail to recognize the importance of becoming involved, especially since they have no peers with whom to discuss their ideas concerning organized medicine and its needs.

Lack of leadership skills development programs. Having a shortage of female role models and of available posi-

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tions, women find it difficult to learn how to play the game of medical politics. Leadership skills development programs hold promise of instilling confidence in individuals in their leadership abilities and of providing some of the tools necessary to be effective leaders.

Longer time to reach leadership potential. Because of family responsibilities, women may not be able to begin a medical political career until a later age than their male colleagues. And by the time they reach the age when family responsibilities are diminishing, women physicians are likely to express feelings of inadequacy and a lack of confidence in their ability to pursue organizational activities. In addition, they have not had the opportunity to develop the power base which is so essential to success. Women's reticence—caused by their lack of experienced self-confidence in this arena—is sometimes interpreted by male physicians as due either to a lack of interest or a lack of willingness to pursue more active roles in the organization.

Competition in medical practice. The forces that have reshaped the practice of medicine in recent years will surely affect the women physician trying to launch her organizational career. Competition in the work place will extend to competition in other areas. With more physicians competing for fewer positions (as well as patients), women may find that they are not aggressive enough to compete successfully. A subtle drawing back from supporting women physicians has already begun.

Commitment. Many women physicians fail to recognize the worth of making an across-the-board commitment to the entirety of medicine, especially since practice and family responsibilities take up such a large part of their lives. It will require an extra effort to get them to understand the value of involvement at all levels of medicine—including participation in organized medicine.

The Challenge Ahead

There are two challenges facing those who champion an increased role for women in organized medicine. The first step is to educate *all* physicians about the importance of belonging to organized medicine. Associations such as the AMA and ASIM represent *the* voice of physicians—a voice that must be heard if the practice of medicine is to survive. But that voice is only as strong as the numbers it represents, and it will grow weaker if less physicians are willing to make the necessary financial commitment. As the numbers of women physicians increase, it will be especially important to make sure that they join these organizations.

The second step will be to integrate fully the women physicians who do join organized medicine into all of its activities. Women members must be urged to accept committee appointments, must be encouraged to accept leadership roles and must be consciously supported if they choose to run for elected office.

Women need to be accepted as leaders before they can prove that they are equal to the task. They also need to be accepted as equal participants in the medical world. The problems facing medicine today are critical for all physicians, both male and female. If those problems are to be successfully resolved, they need to be addressed by all physicians.

SPECIAL NOTICE

Study of Occupational Lung Disease in Connecticut

The American Lung Association of Connecticut is currently undertaking a study to determine the prevalence and distribution of occupationally related lung diseases in Connecticut. Physicians in specialties that may encounter lung diseases will soon be contacted for their assistance in this project. If any possible or probable cases of occupational lung disease are encountered, please report these cases to ALAC. For further information, telephone the American Lung Association of Connecticut: (203) 289-5401.

Adapting to Change Without Destroying Your Practice

LEIF C. BECK, LL.B., CPBC, GEOFFREY T. ANDERS, J.D., CPBC, CPA
AND DOROTHY R. SWEENEY

These are strange times for privately practicing physicians. They are bombarded with warnings that what has been so successful for themselves and their families will soon be totally different. We wrote, for example, recently in this Journal about "coping with change," and *American Medical News* published a major article entitled "Remodeling the House of Medicine," May 17, 1985. The so-called medical futurists tell us that private practice as we have known it will soon be a thing of the past.

And yet most (though not all) physicians we encounter have extremely satisfying careers—professionally, financially and personally. Things are admittedly more complex and the malpractice situation creates a somewhat different mindset, but existing practitioners are generally doing very well. We ourselves agonize over how to justify our own readings of medical practice change, which truly is dramatic, to clients earning well into six-figure incomes with little apparent competition in their specialties and/or service areas.

Is the presently still good situation simply the calm before the hurricane? Do we instead face the early or middle stages of a slowly changing industry in which the "new structure" will take several decades to become the norm? Or will these worries pass by as others have in the past, leaving good physicians able to prosper with loyal patients and secure referral patterns?

A Mixed Bag

We believe the portents of drastic change are real. The number of physicians is clearly becoming greater than the need and the pressures on health care costs will not likely be reversed. These forces of supply and demand combine with entrepreneurs' discoveries that health care is indeed highly profitable to create trends that cannot be turned back.

Medicine is, however, such a fragmented industry—primarily comprising hundreds of thousands of solo and small group practices in a huge array of circumstances—that the apparently inevitable changes come at greatly varied rates. An internal medicine practice in Minnesota fails because of the heavy HMO-PPO inroads, but a cardiology group in a small Pennsylvania city enjoys a near monopoly with no likelihood of incoming competition. A very fine otolaryngology group in a New England city encounters four new ENT "competitors" within six months, while another ENT client in suburban Philadelphia acquires a nearby practice and grows from two to four doctors with an apparently secure practice future. And the forever busy solo family practitioner still has a reception room full of loyal patients who will presumably rely on him until he retires or dies.

Some observers point out that change is accelerating so much that even the presently successful practices are heading for trouble. We agree that the rate of change is increasing, but we expect a so-called "two-tier system" to exist for five, ten or even more years—many continuing successful practices of the old style will coexist (though wither away) with the newer style medical practice *businesses.* Some doctors will thus ride out the changes until they retire or sell out, but younger physicians will have to adapt to the new circumstances in order to stay financially and professionally satisfied for all of their projected twenty or thirty year careers.

While the former group might thus turn a deaf ear to our concerns for the future, most physicians cannot ignore them. Yet what should a solo practitioner or small group practice do differently if he, she or it is faring well at present? Does one tear apart a high-income, successful practice in order to reform it so it can cope with the predicted future? Or, "If it ain't broke, should you fix it?"

Acting Like A Business

Whether physicians like it or not, they are engaged in a *business.* The business is to provide quality medical care compassionately to patients, in return for which profits (or rather, sufficient income to satisfy one's needs) are expected. Medicine is no longer a cottage industry which can ignore business thinking; in fact big business is now a major participant whose involvement is just in its infancy.

Given the situation, medical practices should handle

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themselves more like businesses than ever before. They can do so while still emphasizing quality of care, which we believed will be an assumed "given" in any developing scenario. The concepts of professionalism and profits need not be contradictory.

What characteristics, then, do virtually all other businesses have that are typically lacking in medical practices? Here are some of these traits which we predict will dictate either the long-term success or demise of private practices.

Essential Business-Like Characteristics

1. *An Entrepreneurial Mindset.* While an admittedly vague characteristic, we find that most physicians are woefully lacking in the basic mental approach towards their practices as a business matter. This is not surprising. Doctors typically entered medicine for scientific and/or service reasons, and virtually all their training ignored economics and business management. Now, all of a sudden, these good people are told that their basic thought processes must add an unfamiliar set of ideas.

We expect that young physicians who combine "MBA" programs with their medical educations will become the leaders of many successful group practices in the future. We have similarly encouraged some existing practitioners to seek out business-related courses—perhaps university night programs or several-week summer sessions—in order to acquaint themselves with business concepts. While there are a proliferation of so-called practice management seminars on topics ranging from marketing to computers to personnel, such programs have little value in view of the profound changes taking place.

Whether by additional schooling or by personal self-education, physicians should recognize the need for this extra mindset—"thinking like an entrepreneur." It gives a practice the capacity to appreciate more quickly trends affecting its success; it leads to more decisive action as the so-called "windows of opportunity" open and close; and it fosters receptivity to the various other features upon which all businesses prosper or fail.

2. *Leadership.* Medical group practices, whether two or twenty physicians, routinely function as equal partnerships. Each partner (or shareholder in case of a professional corporation) has an equal vote, and few actions are taken except upon unanimous agreement. In effect, management is so decentralized by respect for each member's position that there is no effective leadership.

Management experts consider it absolutely basic that responsibility and authority vest with a chosen leader—a "chief executive officer." In effect, democracy is the worst form of management!

We are thus urging clients to shift their leadership format from horizontal (all partners are equally in charge) to vertical (authority leading up to a selected chief) as expeditiously as practicable. Some groups have a natural physician-leader who can be delegated real, acknowledged authority. Other groups which lack such an individual or which cannot yet break away from the horizontal style might move towards a two or three doctor "executive committee" as an initial step towards centralizing responsibility.

Physician-leaders cannot, of course, be dictators. A CEO's capacity to decide, lead and take action depends on the partners' consent; he or she loses power without the backing of the constituents. Thus a leadership format enables the group to respond to business problems and opportunities for the members' benefit without really depriving the members of basic control.

As we consult with new client group practices, we tend to feel either optimism or pessimism for long-term success depending on this leadership feature. A common statement among us is, "They're a nice group with a good practice, but I don't see their making needed changes because there's no one to take the lead." Such groups tend to drift, and when crises develop they too often flounder and then splinter away.

Solo practitioners are not immune from the need for leadership. Those doctors who exert it tend to create the strongest, most consistent environment for their office staffs. They also tend to be more affirmative in making practice decisions such as obtaining state-of-the-art equipment and moving to maximally desirable office locations. Besides, we see solo practice diminishing so much in the next few years that leadership will become more and more a matter of group dynamics even for presently successful solos.

3. *Accumulation of Capital.* Businesses spend money to make money. When they have profits, much of the income is retained and plowed back into making future years still more successful. Medical practices, however, usually function differently; as the former president of the American Group Practice Association put it:

> "Most medical groups are designed to go out of business on Dec. 31 of every year. . . . We take all the capital and drain it out and give it to the physicians and then we start all over again on the first of January."

To succeed in this more competitive environment, physicians must have capital; they must be able to invest their earned dollars in their practices. For example, a solo or small group practice might expect to lose $30,000 in the first year of a newly hired physician's employment, but that new doctor might fill a needed role in its longer term success; the support money could be accumulated the year or years before he or she arrives. Or a major marketing effort might require $50,000 or even $100,000 in order to protect a practice's patient base or to develop and negotiate a needed employer health care contract; financing the effort out of accumulated earnings will make the undertaking feasible.

As still another example, we watch the airline companies accept "super saver" rate cuts in order to hold their customer bases for future profitability. Physicians, however, typically flee from virtually any fee concession (including Medicare participation) whether or not patient volume—the lifeblood of a practice's future—will be affected. The concept of accumulating profits in good years and allowing them to be used to support short-term fluctuations as part of long-term business strategies is totally foreign to medical practitioners.

Capital accumulation ties in with borrowing power. Banks are less willing to lend major sums to physicians simply on the basis of predicted future earnings, for those predictions are no longer as reliable. Other types of businesses show their balance sheets including accumulated and reinvested earnings, but medical practice balance sheets are comparatively bare. By accumulating capital, a practice can borrow more funds more favorably for major business outlays; and in turn the repayment of those loans is essentially another form of capital usage.

Doctors would thus be well-advised to leave some of each year's earnings within the practice, thus accumulating a "war chest" for practice development. The strategy would not be a major intrusion on their manner of practice, but it will enable them greater business flexibility in succeeding years. And the accumulated fund would be an "alternate retirement fund" for the practice's owner or owners since the capital value increases one's pay-out upon retirement, disability or death.

4. *Attitude Towards Partnership.* In view of a vastly increasing supply of competent, well trained young physicians, staffing one's practice at the doctor level becomes less difficult than in the past. On the other side, we observe an increasing level of "risk aversion" among residents. More young doctors seem concerned simply for a secure practice position assuring funds to pay off educational loans and support young families than to entrepreneurially build big practices.

With qualified physicians more readily available, the traditional characteristics needed in a partner—clinical ability and compatible personality—become less rare.

As we see it, medical "partnership" should increasingly reflect the special reasons why someone is an owner of a business. The owner controls the sales base (patients and/or referral patterns), manages its operational structure and works hard at building it as a company. The owner's financial rewards are both profits, presumably through salary, bonus, benefits and dividends, and increasing value for ultimate buy-out or sell-off. And the owner, typically of an entrepreneurial mindset, also seeks and cherishes the personal gratification of building a successful business—whether medical or otherwise.

Under such circumstances, every young doctor who is well liked in a practice should not become a partner. The senior physician(s) should make this point clear to prospective and actual associates so they will understand what criteria make the difference. We drafted such a policy statement for a client group along these lines:

> "MEMORANDUM"
> XYZ Medical Associates Policy as to
> Shareholder Status
>
> The corporation no longer promises its new physician-employees invitation to shareholder ("partnership") status after any specific time period of continued employment. While clinical ability is, of course, important to continued practice within the group at all, shareholder status will be offered only to a doctor or doctors having other characteristics important to ongoing success. These characteristics include leadership ability, entrepreneurial interest and performance, research and teaching activity, willingness to expand personal time for the practice's success, etc.

Medical practice is in a transition stage as to this idea. Many successful groups have brought young doctors rapidly and easily into partnership within even the past year or two, and residents are aware of the pattern. Those young doctors also hear of their peers who become generously promoted in the "old style," thus expecting it to be the norm. And yet the changing economics dictate new policies as to practice ownership and income. We thus urge clients to recognize the trend while still being flexible enough to successfully recruit and retain their "first choice" young doctor.

5. *Compensation Policy.* As a practice moves more towards the concept that "ownership" involves capital and entrepreneurialism, it must begin to recognize that an owner's income share should reflect these features. Paying members on their productivity in clinically treating patients ignores the fact that one or more owners are taking business steps to make such production possible—whether by contracting with special patients sources, maintaining important referral relations or directing the practice's major decisions. Besides, how can one be paid on productivity (which encourages greater utilization) if an increasing portion of the practice's patients present themselves under an HMO or other capitated contract?

We sometimes suggest separating a practice's income into its two underlying segments: (1) return on one's medical service, and (2) return upon one's ownership and business responsibility. As an example, for a three-doctor practice we recently suggested that it allocate 30% of its available income (before doctors' compensation) for equal division due to ownership; the balance of the income will be paid to the three physicians either as agreed salaries based on their time seeing patients or on their traditional "productivity." And even the equal division "pot" might in a later year be distributed differently if one of the owners begins to exhibit disproportionate leadership responsibility.

In another case, we recently suggested that a small group become a "Subchapter S" corporation. It would then allocate 10 to 20 percent of its available income (before doctors' compensation) as profits, to be distributed only among the shareholders as dividends, not as salaries. All the remaining income can thus be divided in a traditional medical practice formula, on productivity in this specific case, to recognize the return on patient care service. If a young doctor fails to become a "partner," whether because the capital value price is too high or because the entrepreneurial characteristics are not present, he or she can still be paid fully and fairly for work performed as a capable, respected physician.

We believe these newer approaches towards income division are logically suggesting themselves. Just as with attitude towards partnership, group practices should begin to consider them as they periodically reevaluate their arrangements.

6. *"Think Growth."* Many observers flatly predict the demise of solo medical practice. While we expect some currently successful solo practitioners to maintain their roles for many years, we also expect solo practices to become vastly less common—and less desirable.

Two, three and four doctor groups are not immune. They will be hard pressed to compete effectively for blocks of patients in HMOs or other third party service contracts; they will not be able to afford the expertise of highly paid executive/administrative personnel; nor can they spend comparable funds on marketing, advertising, major new clinical equipment, etc.

As with virtually every other industry, larger companies tend to gobble up or drive out the smaller ones. There is no reason not to expect the same in medicine, for it is no longer a cottage industry. We expect a handful of multi-billion dollar corporations to begin acquiring and managing medical practices in just the next few years, and we specifically know of one such company that is doing so now.

Such circumstances present both major problems and great business opportunities for practicing physicians. On the one hand, doctors can be overrun by the financial clout of practices backed by millions of dollars and scores of capable business executives. How, for example, would even a five-doctor general medicine group retain its patient base if a 25-member group spends $1,000,000 a year on advertising and negotiates a contract with an HMO having quarter of an area's patients?

On the other hand, well respected group practices can think of being bought out for really big dollars. Offers are even now beginning to be seen at two to three times average gross income—in cash—where the practice has special significance to a large entity's business plan. And physicians in some bought-out practices, report that their practice lives have not changed significantly.

Whether to protect oneself against the potential big competitor or to position oneself for the big buy-out, a larger and better integrated practice will have the best chances for success. Two-doctor groups, as mentioned, cannot cope very well compared to a twelve-physician organization; nor will the big institutional buyers be particularly interested in buying up two-doctor groups.

Successful smaller practices might thus be on the lookout for mergers and acquisitions of their own. A solo family practitioner might be alert for compatible colleagues so that a merged five-doctor family practice center will result. A five-member group could in turn tie up with two internal medicine specialists, a surgeon, an allergist, etc. to become a ten-doctor regional medical group. And so on.

We are seeing more practice mergers occurring these days than ever before, and we expect the trend to continue. While some proposed merger should be rejected because the physician-level features, mostly personality, would doom joinder, the business sense of the trend is clear. The resulting groups have vastly increased opportunities for both self-preservation and long-term success than did their component parts.

Similarly, as solo physicians decide to retire from private practice, existing practices are becoming purchasers. Our own process in helping doctors sell their practices involves inquiry and promotion to other practices within or bordering the seller's service area.

The point here is that presently successful practice should be receptive to the possibilities of growing larger, whether by normal development, by merger or by acquisition. Just as in other industries, long term success is more likely for an organization with a greater "market share" for its products or services. Growth cannot be sought indiscriminately—an ill-advised merger may, for example, be disastrous—but its advantages should be recognized so that sensible opportunities are not rejected out of hand.

Conclusion

Physicians who are doing well despite the changing times are sensible not to accept dire predictions out of hand. For the practice that "ain't broke," one should be careful not to fix it too severely. Nevertheless, times do change and our suggested approaches may help many practices adapt and survive while remaining successful during the process.

Leading Work-Related Diseases and Injuries—United States

CENTERS FOR DISEASE CONTROL

The National Institute for Occupational Safety and Health (NIOSH) has developed a list of ten leading work-related diseases and injuries. The first six categories have been described previously, here is a discussion of the seventh and eighth categories.

Neurotoxic Disorders

Background.—Diseases of the nervous system resulting from toxic exposures in the workplace were known as early as the first century AD, when Pliny identified palsy as a manifestation of lead poisoning among workers exposed to lead dust. In 1557, Jean Fernel linked gingival pigmentation, tremor, and behavioral changes to occupational mercury poisoning, in the 19th century, Delpech recognized rubber processing as the cause of the bizarre psychoses occurring among French workers who manufactured condoms and balloons in small cottage industries. Later, carbon disulfide was implicated as the specific neurotoxic agent.

Industrial hygiene practices have improved in the 20th century, and some animal models of neurotoxic disease have been developed. In addition, workers who become ill often draw attention to outbreaks of neurotoxic diseases. Despite the prior identification of acrylamide as neurotoxic in animals, its neurotoxicity in humans was first recognized in the 1950s, when several Japanese workers involved in a pilot production project developed peripheral neuropathy. During the 1960s and early 1970s, dozens of cases of neuropathy occurred among Japanese and Italian workers exposed to solutions containing *n*-hexane during the manufacture of shoes. Subsequently, high doses of *n*-hexane were found to be neurotoxic in exposed animals. In the past 15 years alone, outbreaks of serious human neurotoxicity occurred among workers exposed to three substances not previously known to be neurotoxic: the chlorinated hydrocarbon, chlordecone, which caused opsoclonus, tremor, disturbances of gait, and changes in personality, and two hexacarbons, methyl-*n*-butyl ketone and 2-*t*-butylazo-2-hydroxy-5-methylhexane, both of which caused a predominantly peripheral neuropathy.

Nature of Neurotoxic Disorders.—Neurotoxic disorders are on the NIOSH list of ten leading work-related diseases and injuries because of their potential severity—as exemplified by the neurotoxicity of chlordecone—and because of the large number of workers potentially at risk. A conservative estimate of the workers exposed full time to one or more neurotoxic agents is 7.7 million. The number of potentially neurotoxic chemicals found in the workplace exceeds 850; an abbreviated list of the more commonly used of these chemicals is shown in Table 1.

Clinically, symptoms and signs of neurotoxicity can be diverse. Depending on the intensity of exposure, the molecular configuration of the agent, and the mechanism of toxicity, either central or peripheral neurologic effects may predominate. Most neurotoxic chemicals, however, affect both the central and peripheral nervous systems. Because the symptoms of peripheral neuropathy are more specific and the nerves themselves more directly accessible to precise diagnostic examinations, the effects of neurotoxic agents on the peripheral nervous system are usually more easily identified than effects on the central nervous system (CNS). Early symptoms of peripheral neuropathy may include numbness, tingling, or pain in the feet or hands. As the disease progresses, clumsiness or incoordination due to both sensory and motor changes may develop. Production workers may find their ability to do usual work partially or fully impaired. Chemicals used extensively in industry, which cause peripheral neuropathy when present in sufficiently high and persistent concentrations, include lead, *n*-hexane, acrylamide, carbon disulfide, mercury, and methyl bromide. Several chemicals are known to cause selective impairment of cranial nerve function, including dysfunction of the fifth cranial nerve (trichloroethylene).

The effects of neurotoxic agents on the CNS present a far wider range of disturbances (Table 2). At times, the most striking effects are changes in mood and personality. High levels of exposure to manganese or carbon disulfide produce psychoses and suicidal tendencies. Delusions and hallucinations may result from exposure to high concentrations of solvents, such as methylene chloride. Manifestations of cognitive dysfunction, such as reduced

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—*Morbidity and Mortality Weekly Report*, (Vol. 255, No. 12, 1986).

Table 1

COMMONLY USED INDUSTRIAL CHEMICALS RECOGNIZED AS NEUROTOXIC

- Acetyl ethyl tetramethyl tetralin
- Acetyl pyridine
- Acrylamide
- Adiponitrile
- Alkyl phosphates
- Aluminum
- Aniline
- Arsenic, inorganic
- Arsine
- Aryl phosphates
- Azide
- Barium
- Benzene
- Boron
- *p*-Bromophenyl acetylurea
- Cadmium
- Carbon disulfide
- Carbon monoxide
- Carbon tetrachloride
- Chlordane
- Chlordecone
- Chloroprene
- Cobalt
- Cuprizone
- Cyanide
- 2,4-Dichlorophenoxy acetic acid (2,4-D)
- Dichlorodiphenyl trichloroethane (DDT)
- Diethyl ether
- Diisopropyl fluorophosphate (DFP)
- Dimethyl sulphate
- Ethylene dichloride
- Hexachlorophene
- *n*-Hexane
- Hydroquinone
- Lead
- Lead, tetraethyl
- Leptophos
- Malonitrile
- Manganese
- Mercury
- Methanol
- Methyl bromide
- Methyl chloride
- Methyl *n*-butyl ketone
- Nickel (carbonyl)
- Nitrogen trichloride
- Organochlorine insecticides
- Organophosphate esters
- Organotins (triethyltin)
- Paraquat
- Phenol
- Phenyl mercury
- Phthalate esters
- Polybrominated biphenyls (PBB's)
- Selenium
- Styrene
- Sulfur dioxide
- Tetrachlorobiphenyl
- Thallium
- Toluene
- Trichloroethylene
- Triorthocresylphosphate (TOCP)
- Vanadium, inorganic salt
- Zinc
- Zinc pyridinethione

Table 2

CLINICAL MANIFESTATIONS AND CAUSES OF CENTRAL NERVOUS SYSTEM (CNS) CONDITIONS

Condition	*Symptoms*	*Signs*	*Latency*	*Prognosis*	*Substances*
Acute Conditions					
Acute intoxication	Dizziness, lightheadedness, balance and gait impairment, incoordination, and feeling "high."	Ataxia, slow psychomotor function.	Minutes-hours	Reversible	Organic solvents, inhalation anesthetics
Acute toxic encephalopathy	Obtundation, coma, seizures, potentially fatal.	Signs of diffuse CNS depression, reflex slowing, EEG slowing.	Hours-days	Persistent deficits common	Solvents, lead, pesticides
Chronic syndromes					
Symptoms only	Mood changes (irritability, depression), sleep disorders; difficulty concentrating; memory complaints; symptoms are more noticeable to relatives than to patient.	No objective signs.	Weeks-months	Reversible	Carbon disulfide, lead, organic solvents
Mild chronic toxic encephalopathy					
Organic personality or mood disorders	Similar to those noted above but of greater frequency and severity.	Alterations in mood or personality.	Weeks-months	Incomplete reversibility possible but uncommon	Lead, organic solvents
Neurobehavioral impairment	Symptoms as above.	Reduced motor speed, reduced vigilance and reaction time, plus reduced performance on memory (short-term) testing and other tests of cognitive function (ie, visuospatial ability).	Weeks-months	Potentially reversible, partial or complete	Carbon disulfide, lead, organic solvents, possibly carbon monoxide
Severe chronic toxic encephalopathy (dementia)	Significant loss of ability to perform activities of daily living; difficulty in comprehension, profound memory loss, reduced verbal fluency.	Testing compatible with severe neurologic damage and neuropsychologic impairment as seen in dementia.	Unknown	Poorly reversible	Lead, organic solvents

attention span, lack of alertness, and memory loss, are prominent neurotoxic effects that may occur in addition to personality changes after exposure to many solvents and to asphyxiants, such as carbon monoxide. Other neurologic effects occur under certain restricted conditions of exposure to unique chemical substances (Table 3).

Table 3
OTHER NEUROLOGICAL EFFECTS

Health effects	*Agents*
Motor and gait disorders	
Ataxia	Acrylamide Chlordane Chlordecone DDT *n*-Hexane Manganese Mercury (especially methyl mercury) Methyl *n*-butyl ketone Methyl chloride Toluene
Myoclonus	Benzene hexachloride Mercury
Paraplegia	Organotin compounds
Parkinsonism	Carbon disulfide Carbon monoxide Manganese
Seizures	Lead Organic mercurials Organochlorine insecticides Organotin compounds
Tremor	Carbon disulfide Chlordecone DDT Manganese Mercury
Visual-system effects	
Nystagmus	Mercury
Opsoclonus	Chlordecone
Constricted visual field	Mercury
Impaired visual acuity	*n*-Hexane Mercury Methanol

Although research into the neurobehavioral effects of industrial chemicals is relatively new, early results suggest that occupational neurotoxicity may be a larger problem than previously suspected. Sensitive methods for evaluating subtle losses in cognitive function have only recently been applied to the evaluation of exposed workers. Because of the complexity of the nervous system and the variety of potentially neurotoxic exposures, the true scope of this health hazard in the workplace is unknown.

Reported by Div of Biomedical and Behavioral Science, Div of Surveillance, Hazard Evaluations, and Field Studies, National Institute for Occupational Safety and Health, CDC.

CDC Editorial Note: Studies of the neurotoxicity of workplace chemicals demonstrate the problems encountered in recognizing occupational disease in general. Despite occasional large and dramatic outbreaks of neurotoxic disorders, such as those mentioned above, more often small numbers of workers in many workplaces are chronically exposed to neurotoxic agents that subtly and slowly alter nervous system functions. Several neurotoxic syndromes mimic diseases of nonoccupational and "idiopathic" etiology; for example, the toxic axonopathy associated with exposure to various metals and solvents, the parkinsonian syndrome of chronic intoxication with manganese, and the organic brain syndrome of chronic solvent intoxication. Because of these similarities to other nonoccupational diseases, such cases are frequently not identified as occupational in origin. In addition, many physicians are not trained to take an adequate occupational medical history. For these reasons, the prevalence of occupational neurologic disease is unknown, and important casual relationships between chemical and disease remain obscure.

The prevention of neurotoxicity among workers will require strategies such as those suggested in the 1990 objectives for improving the nation's health, developed by the Public Health Service: (1) analyses of structural analogues of known neurotoxic agents in an effort to predict the neurotoxicity of untested chemicals; (2) continuing search for animal models of disease; (3) ongoing research in establishing an acceptable human exposure level for identified neurotoxic agents; (4) epidemiologic evaluations of suspected neurotoxicity; (5) development of simple screening tools for use on asymptomatic populations exposed to known neurotoxic agents; and (6) premanufacture and premarket testing of new chemicals as required by the Toxic Substances Control Act. As in the prevention of other work related diseases, however, the most direct and effective method for preventing neurotoxic illness will continue to be the environmental control of exposures to neurologic chemicals. Such efforts as the substitution of less toxic substances where possible, engineering controls, teaching appropriate work practices, and educating workers about the potential neurotoxicity of chemicals will aid a comprehensive prevention effort.

Noise-Induced Loss of Hearing

Occupational deafness was first documented among metalworkers in the 16th century. Since then, workers have experienced excessive hearing loss in many occupations associated with noise. Typical occupational and nonoccupational noise levels are shown in the figure. Noise-induced loss of hearing is an irreversible, sensorineural condition that progresses with exposure. Although hearing ability declines with age (presbycusis) in all populations, exposure to noise produces hearing loss higher than that resulting from the natural aging process; this is caused by damage to nerve cells of the inner ear (cochlea) and, unlike some conductive hearing disorders, cannot be treated medically.

While loss of hearing may result from a single exposure to a very brief impulse noise or explosion, such traumatic losses are rare. In most cases, noise-induced hearing loss is insidious. Typically, it begins to develop at 4,000 hertz (Hz, or cycles per second) in the hearing range of 20 Hz to 20,000 Hz and spreads to lower and higher frequencies. Often, material impairment has occurred before the condition is clearly recognized.

Such impairment is usually severe enough to permanently affect a person's ability to hear and understand speech under everyday conditions. Although the primary frequencies of human speech range from 200 Hz to 2,000 Hz, research has shown that the consonant sounds, which enable people to distinguish words such as 'fish' from 'fist,' have still higher frequency components. As a result, an average hearing threshold (lowest audible sound level) at separate frequencies of 1,000 Hz, 2,000 Hz, and 3,000 Hz, is used widely to define material impairment caused by noise.

Recent estimates by the Occupational Safety and Health Administration (OSHA) indicate that about 9,400,000 US production workers (7,900,000 active and 1,500,000 retired) either now work or have worked in industrial locations where noise exposure levels are 80 decibels (dB) or higher. This estimate includes most noisy workplaces in the United States, except agricultural, mining, construction, transportation, and government (Table 4). At exposure levels below 80 decibels (weighted to the approximate response of the human ear, dBA), an increased risk of hearing loss caused by occupational noise has not been found. Based on the average hearing threshold level at 1,000 Hz, 2,000 Hz, and 3,000 Hz, OSHA estimated that 1,624,000 (17%) production workers have at least mild hearing loss resulting from their occupational noise exposures; 1,060,000 (11%) have material hearing impairment; and 473,000 (5%) have moderate to severe impairment (Table 5). These estimates generally agree with NIOSH survey findings, which indicate that one fourth of persons 55 years of age or older who have been exposed over their working lifetime to an average of about 90 dBA have developed a material hearing impairment caused by occupational noise exposure. An estimated $835 million will be paid in workers' compensation claims for occupational hearing impairment for the ten-year period 1978-1987.

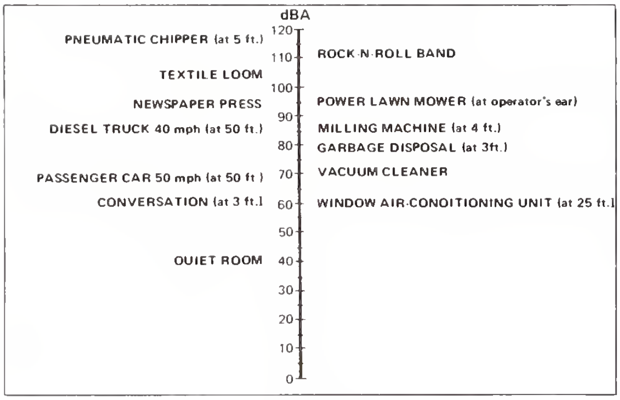

Figure
Typical A-weighted noise levels in decibels (dBA)*

*The decibel is a logarithmic measure of sound intensity; the "A-weighted scale" is used to weight the various frequency components to the noise to approximate the response of the human ear.

Reported by Physical Agents Effects Br, Div of Biomedical and Behavioral Science, National Institute for Occupational Safety and Health, CDC.

Table 4
DISTRIBUTION OF 9,368,000 PRODUCTION WORKERS WHO HAD NOISE-EXPOSURE LEVELS OF 80 dBA OR GREATER*—UNITED STATES

Noise-exposure level (dBA)	*No. workers*
80-85	3,305,000
86-90	2,656,000
91-95	1,936,000
96-100	965,000
>100	506,000

*From the 1981 OSHA Final Regulatory Analysis for the Hearing Conservation Amendment.

Table 5
HEARING LEVELS (DECIBELS—dB) OF 9,368,000 PRODUCTION WORKERS WHO HAD NOISE-EXPOSURE LEVELS OF 80 dBA—APPROXIMATE HUMAN EAR RESPONSE—OR GREATER*—UNITED STATES

Hearing threshold level (1,000, 2,000 and 3,000 Hz)	*Cumulative cases* (%)	*Expected cases*† (%)	*Excess cases*§ (%)
>15 dB (mild hearing loss)	3,735,000 (40)	2,111,000 (23)	1,624,000 (17)
>25 dB (material hearing impairment)	2,025,000 (22)	965,000 (10)	1,060,000 (11)
>40 dB (moderate to severe hearing impairment)	718,000 (8)	245,000 (3)	473,000 (5)

*From the OSHA 1981 Final Regulatory Analysis for the Hearing Conservation Amendment.
†Based on hearing levels of a nationwide sample of adults in Public Health Service hearing surveys.
§Cumulative cases minus expected cases.

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Editorial

Biology of Organ Transplantation

Since antiquity, man has dreamed of curing various bodily ills by removing a damaged tissue or organ and replacing it with a normally functioning substitute. Thus the Chinese surgeon Pien Ch'iao is reputed in the second century B.C. to have painlessly and successfully exchanged the hearts of two patients. Nevertheless the results of such a procedure might be hazardous even in those days; e.g. the ancient Greeks reportedly knew and feared creation of a chimera, literally a mixture of tissues from different individuals, since this was a malignant she-monster composed of a lion's head, a goat's body and a dragon's tail, and which vomited flames.

However, it is only within our own times that the longheld philosophers' claims that we are all individuals with unique characteristics were shown scientifically to clearly have a biological basis. Indeed, these largely inheritable differences, readily detectable by immunological methods at the cellular level, arise from the actual genetic code, and inexorably lead to rejection of foreign or "nonself" cells or tissues. It is one of the triumphs of modern medicine that transplantation of several organs is now both possible and practical. The two papers by Bow and Schweizer,[1] published in the July and August issues of *Connecticut Medicine*, describe in detail the biological basis for differences between individuals, and how these may be overcome in the clinical setting to achieve successful organ transplantation.

The particular membrane glycoproteins responsible for these effects are known as transplantation antigens, and are products of a region on the sixth chromosome known as the major histocompatibility complex (MHC). The nature and distribution of these antigens is currently an area of intense research. The two main types of MHC antigens are called Class I (or HLA-ABC) and Class II (or HLA-D/Dr) antigens. Class I antigens appear to be expressed on most cell types and are the usual target of the immune response to a grafted organ (known as an allograft). Class II antigens have a more restricted distribution and are particularly important in the initiation of an immune response. Recent research has emphasized that the levels of both Class I and Class II antigens can be increased by the action of the lymphokine gamma-interferon, and that this induction by gamma-interferon is one of the body's tricks for accelerating the rejection process. Conversely, reduction in the Class II antigen content of an organ such as the pancreas, through experimental means, can markedly enhance pancreatic engraftment.

In addition to matching for MHC antigens, theoretically prevention of an immune response to an allograft can be attempted by pretreatment of either the graft itself or the recipient. Bow and Schweizer discuss how pretreatment of an individual to reduce their likelihood of responding adversely to a graft is currently largely restricted to the use of blood transfusions, though the precise mechanisms responsible for this beneficial effect are unknown. Experimental manoeuvres to decrease the Class II antigen content of a given tissue before grafting, through tissue culture as mentioned above or through application of cytotoxic antibodies directed against Class II antigens, are under investigation and may play a role in clinical transplantation in the near future. Alternately, suppression of an immune response to the graft can be attempted once rejection has begun. Immunosuppression and treatment of acute rejection is currently achieved with corticosteroids, cytotoxic agents such as azathioprine, or the recently introduced and highly efficacious fungal metabolite cyclosporin. In addition, it is likely that treatment of acute rejection with monoclonal antibodies will also soon become a standard mode of therapy.

As discussed by Bow and Schweizer, the choices in organ transplantation are to find a living related donor such as an identical twin, or a closely related individual who presumeably will show minimal MHC differences, or to find the best match possible through regional or national transplant matching services. The latter approach using cadaveric transplants has been very succesful in this and many other countries. Current figures from the New England Organ Bank, which plays a central role in matching and monitoring the rate of organ transplants in the six New England states, indicate that over 400 organ transplants are performed in the region each year. e.g. in May 1986, 44 organ transplants were recorded, consisting of 31 kidney transplants, 6 liver transplants, 4 heart transplants, and 3 pancreatic transplants. The rate of organ transplants may be expected to rise as the public awareness of the importance and success of organ transplantation increases. This can be achieved through publicity events such as Donor Awareness Week, inclusion of relevant literature in license renewals and other promotions. Similarly and equally importantly, the 2 papers included here should contribute to increased knowledge and confidence in this approach by primary care physicians everywhere.

Wayne W. Hancock, M.D. PhD.

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Inaugural Address of the Incoming President

Annual Meeting — House of Delegates

May 17, 1986

JOSEPH C. CZARSTY, M.D.

It is with a great sense of pride that I address you today as the new president of the Connecticut State Medical Society. I consider the opportunity to serve in this capacity for the next year a distinct privilege, and I want to thank each and everyone of you for your vote of confidence in me.

Organized medicine is going through some very difficult times. We have been fortunate during the past year to have as our President a physician who has been dynamic and innovative. Bill Whalen has represented us well at the grass roots of the medical community, in front of the legislature and government agencies, and wherever the Society has asked him to go and speak for Connecticut physicians. He is going to be a hard act to follow. He deserves our upmost thanks, and I would ask for a standing round of applause before I continue my remarks.

As we face the coming year, it is necessary to reassess some of our programs, move ahead with others, and investigate new territories where dynamic new efforts are required. Our Leadership Conference of the past year was a huge success, and it will be repeated with an expanded guest list. Meetings between county presidents and state officers will also be continued because the cooperation among all levels of organized medicine is closely tied to any success we may achieve.

While I have heard a certain amount of doom and gloom as I attended medical association meetings on the regional and national level during the past few months, I remain an eternal optimist. I believe sincerely that medicine will survive this period of turbulence and that the practice of medicine will remain rewarding, both intellectually and monetarily. In order for this to happen, medicine must close its ranks and act as a unified body. There is no place in our Society for disruptive arguments among specialties. As far as I am concerned, when one specialty is threatened, the entire family of organized medicine is threatened.

People have asked me over the past few months what the focal point of my administration will be. Obviously, this is a difficult question because of the many problems confronting our profession. Yes, I am concerned with malpractice and tort reform issues. Yes, I am concerned with the proliferation of IPA's and HMO's. Yes, I am concerned with the development of alternative health care delivery systems which may or may not produce the quality of care that is characteristic of the american medical system. Yes, I am concerned with the competitive environment and the pressures physicians are facing.

When I look at all these I keep coming back to the issue of quality of care as the one that troubles me the most. As physicians, our primary responsibility is to our patients. We must continue to be their advocate and see that they receive the best possible care, no matter what those around us are advocating. We have all seen increased competition for patients and as this continues we may well experience shrinking appointment schedules. Obviously, this may result in falling revenues. In many areas, there is a physician surplus. Hospitals faced with a declining patient load are becoming more competitive with the private physician and attempting to offer new services to the public in order to maintain a line of referral for their particular institution. Walk-in clinics, which are staffed by members of our profession, offer another type of health care delivery which represents competition to those of us in private practice. another area of competition which probably troubles me the most is that which is coming from non-physicians. The Connecticut Legislature in its wisdom is placing more and more credibility on those who offer a health care service, but do not have a medical degree. As time passes, I am afraid that non-physician suppliers such as midwives, nurse practitioners, optometrists, chiropractors, podiatrists, psychologists, and other similar practitioners will become more aggressive in their attempts to practice medicine without a medical license. In the April 9, 1986, edition of USA TODAY, there was a feature story about a new Florida law on prescriptions which will allow Florida pharmacists to dispense certain prescription drugs without a doctor's order. The law is probably already in effect, and we can look for similar proposals to surface in Connecticut in the relatively near future.

Incursions into medical care probably represent the greatest threat to our survival as a profession as well as to the quality of care which is expected of us. Therefore, I call on the Connecticut State Medical Society to monitor carefully legislative developments which erode the base of our medical practice, and I call on each of you as physicians to deliver care with a special kind of caring. We must be perceptive to the needs of our patients and also what our patients perceive their needs to be. Adaptability will probably be the key word in managing our practices in the future and in serving our patients. Let us make sure that we continue to do the job we have been trained to do.

Thank you very much!

JOSEPH C. CZARSTY, M.D., incoming President of the Connecticut State Medical Society is in the Private Practice of Family Medicine, Oakville, CT.

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Reflections on Medicine

Hence Loathèd Melancholy

ROBERT U. MASSEY, M.D.

Last month I mentioned Democritus, the laughing philosopher and his assertion that *euthymia* or cheerfulness was the first principle of ethics. While Democritus may have laughed at the follies of mankind, others who knew him wrote of his sadness.

Robert Burton, author of *The Anatomy of Melancholy*, which Osler called "a medical treatise, the greatest indeed written by a layman" introduced himself as "Democritus Junior." He observed that Hippocrates had described Democritus as "a little wearish old man, very melancholy by nature, averse from company in his latter days, and much given to solitariness," but later, continuing to quote Hippocrates, he noted "that sometimes he would walk down to the haven and laugh heartily at such a variety of ridiculous objects, which there he saw."

Burton, like Milton, recognized the two faces of melancholy, its gloomy repulsiveness as well as its sometimes fatal attraction:

"When I go musing all alone,
Thinking of divers things fore-known
When I build castles in the air,
Void of sorrow and void of fear,
Pleasing myself with phantasms sweet,
Methinks the time runs very fleet.
  All my joys to this are folly,
  Naught so sweet as melancholy.
When I lie waking all alone,
Recounting what I have ill done,
My thoughts on me then tyrannize,
Fear and sorrow me surprise,
Whether I tarry still or go,
Methinks the time moves very slow.
  All my griefs to this are jolly,
  Naught so sad as melancholy."[1]

Recently at a meeting of physicians and hospital leaders someone likened our present state of mind to a reactive depression and suggested that we might shake ourselves loose by examining the causes of our discontent and resisting the temptation to exaggerate them. At least, he said, that is what we would tell our patients. Most nodded assent to the diagnosis, not all agreed that the causes had been exaggerated or the cure so easy. Since the depression was not of long standing, we might draw hope from Burton:

"If this malady be not herditary and taken at the beginning, there is good hope of cure." Quoting another authority he wrote: "Hildesheim holds it less dangerous if only 'imagination be hurt, and not reason.'"[2]

One physician said he would discourage his children from considering a career in medicine; another that he would never have become a doctor if he had known what he now knew. "I feel that everything that has happened has driven me farther and farther from my patients—new technology, new regulations, DRGs. Some green eyeshade questions every professional decision I make, and when I try to explain, he doesn't know what I'm talking about. Who wouldn't be depressed? And then the lawyers. . . ."

But as we talked it became clear that the only essential actors in the play after all were doctor and patient; that relationship at least remained though its quality may have changed. All the other actors could and would come and go from the stage; everything else would ebb and flow in the manner of plays and history: doctor and patient would remain to the end, even outlasting stage and theater. In fact the team of doctor and patient had written and produced the play, as well as being the actors in it. They were the irreducible dualities like man and wife, mother and child, teacher and student. "The doctor still remains the linch-pin of the entire medical system," Dr. Whalen wrote in this Journal two months ago.[3]

That insight seemed to help; none of those others are able to do what we can do; they cannot take care of patients without us. Business coalitions cannot remove a malignant tumor, Medicare officials cannot make a diagnosis or direct a course of therapy, lawyers cannot read a pyelogram. Doctors are clearly not powerless in the coming struggle to control the organization of medical services. Their representatives must be present and voting wherever the decisions are made; only through their professional organizations, however, can they speak from a position of power; only backed by their science and their high principles can they speak with authority. Burton would have agreed that cheerfully taking charge is the best remedy against discontent.

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ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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Abortion 1986: State Constitutional Perspectives II

JOSEPH M. HEALEY, J.D.

Over the past few years, there has been a shift in legal tactics by those seeking to establish that the state has a legal obligation to fund all medically necessary abortions. Frustrated by an inability to establish a basis for this claim in federal constitutional law, proponents of this position have redirected their efforts to state courts and to state constitutional law. In a recent Connecticut case,[1] the Superior Court for the Judicial District of New Haven considered such claims in light of various provisions of the Connecticut state Constitution. At issue in this case was the constitutionality of a state regulation prohibiting the use of state funds except when the life of the mother is threatened or when pregnancy is the result of rape or incest. This month's column will conclude discussion of this case begun last month.

In his opinion, Judge Robert Berdon concluded that the regulation providing for the funding of abortion under the Medicaid program only when necessary to preserve the physical life of the woman or when pregnancy is the result of rape or incest was in violation of the rights of poor women and physicians under Article First, Sec. 10 of the Constitution of the State of Connecticut and Article First, Sec. 1 and 20 (including the Equal Rights Amendment, Article Five of the Amendments) of the Constitution of the State of Connecticut. He required the state to pay for the costs of all medically necessary abortions on the same basis, to the same extent and with the same limitations as it pays for all other medical expenses under the Medicaid program.

Judge Berdon's opinion was based upon his conclusion that there exists a right to freedom of procreative choice, part of the right of privacy implicit in the concept of liberty in the due process clause of the state constitution. This right is parallel to the rights in reproductive matters recognized in the United States Constitution, though it need not be the same in all respects. This right is not absolute and was examined by the trial court to see whether any sufficient state interest outweighed it. Judge Berdon found no such interest present and held the state regulation to be unconstitutional. On a second constitutional basis, Judge Berdon explored the relevance of the state constitutional equal protection clause and Equal Rights Amendment. He pointed out that the regulation discriminated on the basis of sex in several ways. First, the Medicaid program provided all the medical expenses necessary to restore males to health and females to health except for therapeutic abortions that are not necessary to save the woman's life. Second, all the medical expenses associated with reproductive health and family planning for males and females were covered except for medically necessary abortions when pregnancy does not endanger the woman's life. Finally, since only women become pregnant, discrimination against pregnancy by not funding abortion when it is medically necessary and when all other medical expenses are paid by the State for both men and women is sex-oriented discrimination. Judge Berdon found no compelling state interest to justify this discriminatory treatment and, hence, concluded that the state regulation was also unconstitutional on this second ground.

The decision of Judge Berdon is of limited precedential value in its present form. If appealed, the state Supreme Court would have the opportunity to address the nature of the right of privacy under the Connecticut Constitution and to provide guidance for its application in health law contexts. Regardless of what happens, Judge Berdon has provided a scholarly, comprehensive examination of a contemporary legal issue which remains the center of societal controversy.

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JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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Letters to the Editor

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IS SILENCE ASSENT?

To the Editor: Your editorial in the April issue [1] criticizes an "article" of mine which is not in fact an "article" but the unpublished transcript of testimony I gave last January in a hearing on impaired physicians held by the Council of the City of New York.

Unfortunately, since the transcript is not published, your readers do not have the opportunity of reading for themselves what I really said. If they did, I am sure most of them would question whether your selective interpretation of my remarks was accurate.

Let us consider your "two very strong objections" to what you describe as my "stated position."

First, you object to my "assumption" about the number of impaired physicians because I gave "very little reasoning as to how (I) arrived" at the estimated number. Anyone reading my actual testimony would immediately see that I disclaimed any personal knowledge of the correct number. I merely said that estimates of 5% to 10% of practicing physicians (incompetent, impaired or otherwise unfit) had been made by others and I really didn't know what the correct figure was. It was the media who played this up and made it appear as if I were claiming to be the authority on this matter. Everyone agrees there is some small percentage of practicing physicians who are not qualified, but no one knows how numerous they are. Whatever the number, surely most of us would also agree that the system for dealing with this problem can, and should, be improved. That is what I emphasized in my testimony.

Second, you imply that I said malpractice suits are an indication of professional incompetence. If you reread my testimony, I am sure you will see that I twice pointed out that litigation is *not* a reliable way of identifying incompetent physicians. Indeed, in all my public statements on this issue, I have stressed that the present system confuses two distinct problems: "maloccurrence" (i.e., iatrogenic injury) and "malpractice" (i.e., professional negligence). In my view these problems need quite different solutions, neither of which is likely to be found in the courtroom.

Although I do not share your confidence that the "marketplace" will eliminate unqualified physicians, I do agree with your general criticisms of the tort system and with your conclusion that "the medical profession must maintain and increase its peer review and credentialing process at an even higher level."

We need to recognize that the public and government are not going to support tort reform unless they are convinced that the profession is doing everything within its power to police itself. Improvement in peer review will of course require more help from government (including protection against legal counteraction) but it also will require more determined action by us. It isn't that we haven't tried—of course we have, with impressive results in at least some states—but the evidence suggests we can do better. [2] This is no time to be complacent or overly defensive about our responsibilities for peer review.

Arnold S. Relman, M.D.

Editor, *New England Journal of Medicine*

The above letter was referred to the editor, author of the article who offers the following reply.

I was pleased to receive the above response from Dr. Relman regarding the editorial "Silence Is Assent" which appeared in the April issue of *Connecticut Medicine.*

The remarks in this editorial were addressed to testimony given by Dr. Relman on January 21, 1986 in regard to impaired physicians held by the Council of the City of New York. I honestly do not believe that anybody has tried to "sweep under the rug" the fact that there are a number of incompetent physicians, who still are in the practice of medicine. As I have stated previously, I truly feel that we are, possibly belatedly, doing very much toward the goal of minimizing and hopefully eliminating this problem in our medical community. I also continue to feel that the numbers given by Dr. Relman in his testimony are far out of line of the experience that many of us have had in dealing with this matter at close quarters for many years. As the old saying goes, when you "give a dog a bad name, everybody kicks it." The media has seen to the fact that this has happened. Admittedly, some of the adverse comments of the media were taken out of context from Dr. Relman's testimony.

In regard to this matter of incompetence being closely aligned with malpractice matters, the following is submitted. In Dr. Relman's testimony, he states "the malpractice question is so closely connected with the problem of incompetent physicians, that a few comments are in order." He further goes on to state that "investigation of the physician may be initiated by a report of an adverse event, unfavorable decision in a malpractice suit, an action taken by peer review committe, or complaint lodged by a patient or colleague." The question of a physician's negligence, like the more general question of fitness to practice, is best decided by a legally empowered panel of his peers which should also include representatives of the public and legal profession, such as by state board." The problem with this philosophy is that, as commonly known, the highly trained senior physician or academician may well fall into the slot simply on the basis of his management of high risk cases, more complex diagnostic and surgical measures employed by virtue of this role. As an example, the high number of physicians who have been sued, would seem to indicate a high expectation on the patient's part, litigation prone society and many other matters other than poor performance by the physician.

Thus the case of aligning medical malpractice cases with incompetent physicians has *not* been made. I submit that the terminology in his testimony tends to lead one to this erroneous conclusion. The problem with criticism given in this type of testimony is that it is given such widespread notoriety by the media that it hurts our attempts toward tort reform and other related issues. Much has been written about the way litigation has interfered with licensing of day care centers, recreational facilities, high school athletics, local parks, etc. as well as city police, and fire department coverage. The unavailability of reinsurance money has made it truly difficult to operate a professional liability insurance program.

It is most difficult to obtain proper legislative relief for these problems and for the problem of physicians leaving practice, because the public perception is one of greedy, incompetent physicians undertaking their care. It is my contention that self criticism and improvement of the performance of the physician should be carried out on a different basis than that given in the unfortunate (and I submit inaccurate) previously mentioned testimony. It is difficult to stand idly by and let this happen to us, thus the editorial was entitled "Silence Is Assent."

Stewart J. Petrie, M.D.

Editor Pro tem,
Connecticut Medicine

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Clinically Relevant Factors in Transplantation Immunology

(Second of Two Parts)

LAURINE M. BOW, M.S. AND ROBERT T. SCHWEIZER, M.D.

Overview of Part Two

Organ transplantation will be greatly simplified if methods could be developed that would permit the recipient to accept the graft as a natural part of himself. That is, the foreign antigens in the graft would be accepted as part of the recipient—a "tolerant" state. This condition can often be induced in the experimental animal by injection of antigens, but the tolerance cannot be consistently induced in adult animals receiving organ transplants.

A simple manuever increasing organ transplant survival and resembling a partial tolerant state is the administration of leukocytes from an individual, not necessarily those of the organ donor, prior to the organ transplant. The leukocytes contained in an ordinary blood transfusion will suffice, but the mechanism is even stronger if the leukocytes are from the perspective kidney donor. This latter situation exists when a relative donates a kidney since there is ample time to administer the blood and wait for a protective effect.

The mechanisms whereby these transfused lymphocytes aid graft survival is not known. Two possible explanations are the development of specialized lymphocytes, T suppressor cells, or the production by the recipient of a very specific antibody called anti-idiotypic antibody. This antibody is made in the recipient and may bind to areas on the surface of the recipient's lymphocytes that are directly involved with the rejection attack, turning off that process.

The current primary method to induce acceptance of an organ transplant is by the combination of medications directed at the recipient's immune defense mechanism. For example, the combination of an antimetabolyte, azathioprine, and a corticosteroid have permitted long term survival of 50% of cadaver kidney transplants. More recently, cyclosporine has been added to that combination. This has resulted in a marked increase in success of all types of organ transplants.

Another new development is the use of antibodies prepared from cultured cells and directed against lymphocytes specifically involved in the destruction of the organ transplant. An older type of antibody preparation made in horses or rabbits is less specific, but is still useful in certain circumstances. Unfortunately, these biological preparations have inherent problems. Nevertheless, this type of therapy has considerable promise for future important advances in the control of the rejection process.

PART TWO

The first part of this review in the July issue of *Connecticut Medicine* presented many of the details of the immune response to an organ transplant. If unmodified, the rejection process will rapidly destroy the transplant. We have previously discussed methods to diminish the rejection phenomenon by decreasing the antigenic disparity between the donor and the host, i.e., tissue typing and matching, and also by elminating strong histocompatible antigens in the donor *via* passenger leukocytes (dendritic cells). The more common method of preventing rejection is through chemical immunosuppression. This involves the administration of medications such as corticosteriods, cyclosporine, azathioprine, antithymocyte globulin, and other somewhat toxic modalities.

An alternative to immunosuppression, and sometimes an adjunctive measure, is to alter the immune response of the host through prior exposure to histocompatible antigens. Experimentally, this can be accomplished with pure antigen extracts, especially in rodents. In man, however, this technique has been limited to antigens given by way of blood transfusions or a concentration of leukocytes. While this method is not as effective as chemical immunosuppression, it has the tremendous advantage of diminishing the need for high dose immunosuppression. With further investigation, this concept has the potential of eliminating the need for chemical immunosuppression.

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Blood Transfusion and Transplantation

Pre-transplant blood transfusions have been shown to be one of the most significant factors effecting transplant survival.[1] Patients who have never received a blood transfusion and are transplanted with a cadaver kidney have chances for graft survival diminished by almost 20%, as shown in Figure 1. This dramatic effect was first recognized in the early 1970's, when the policy of most transplant centers was to avoid transfusing their prospective kidney transplant recipients if at all possible.[2] This policy was instituted because approximately 10% of patients respond to the blood transfusions by forming cytotoxic antibody against the HLA antigens carried on leukocytes in the blood. The presence of cytotoxic antibody to donor HLA antigens at the time of transplant will cause the kidney to irreversibly fail within minutes, a so-called *hyperacute* rejection. This hyperacute rejection is most likely due to antibody and complement binding to the histocompatible antigens residing on the kidney tissue. Therefore, the patients who develop those antibodies can only be transplanted with kidneys they do not have antibody against, which consequently lowers their chances for ever receiving a kidney transplant.

With these complications in mind, it was easy to see why blood transfusions were considered detrimental and thus avoided. As a result of the decreased number of patients being transfused prior to transplant, one year cadaver kidney transplant survival rates also decreased. In 1975, when the percentage of non-transfused patients was highest, the graft survival rate was lower than at other periods. It is now the policy of most centers to deliberately transfuse their patients prior to transplantation, if they have not already received transfusions. As can be seen in Figure 1, the optimal number of transfusions is approximately six.

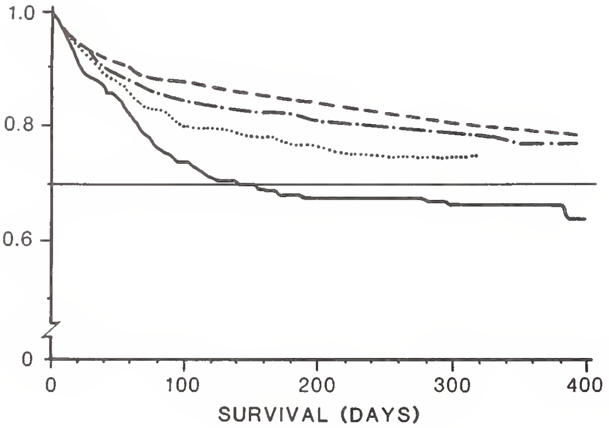

Figure 1

Effect of pre-transplant blood transfusions in patients receiving cyclosporine. Fraction of grafts surviving (vertical axis) are shown for patients receiving 0 transfusions, (———), 1 transfusion (• • • •), 2-10 transfusions (▬•▬•▬), and greater than 10 transfusions (▬ ▬). Approximately 4,000 patients were evaluated.

Despite the beneficial effect of blood transfusion prior to cadaveric kidney transplantation, concern about sensitization against HLA antigens remains. It is therefore important to limit the number of transfusions, and also to carefully consider a transfusion policy for the individual patient. For example, a multiparous woman who has already formed cytotoxic anti-HLA antibody as a result of the pregnancies should not receive blood transfusions. She would most likely respond to even a few blood transfusions with a very broad and high titer of cytotoxic antibody. Another consideration is that cyclosporine has markedly improved results even in non-transfused recipients of cadaveric kidneys.

Donor Specific Transfusions

Given the fact the transfusions are beneficial to cadaver kidney transplant survival, a protocol was developed by Salvatierra and associates which consisted of transfusing recipients with blood obtained from their prospective living related kidney donor.[3] Three 200 ml transfusions are given at two week intervals. If cytotoxic antibody does *not* develop as a result of these transfusions, the transplant is performed approximately six weeks after the last transfusion. Graft survival rates in these patients are truly remarkable, approaching 95% at one year. Without such transfusions, graft survival is only about 75% at one year.

However, the complication of antibody formation is even more important in this group of patients. Most centers utilizing the donor specific blood transfusion protocol report the frequency of patients forming antibody against the donor HLA antigens to be around 30%. Different methods have been tried to lower this sensitization rate, such as the use of stored blood to decrease immunogenicity,[4] administration of azathioprine concurrent with the blood transfusions,[5] and decreasing the number of transfusions to two.[6] These methods have all been shown to have an effect on the frequency of antibody formation, but it is not clearly known if the beneficial effects of the transfusions will be maintained. Data from patients receiving these protocols obtained in the next few years will hopefully answer this question.

Mechanisms of the Blood Transfusion Effect

Although it has been documented since 1975 that pre-transplant blood transfusion clearly diminishes the host's immune response to the transplant, the exact mechanism by which this occurs remains elusive. It has been argued that blood transfusion was simply a way of selecting "non-responders", i.e., those patients who responded to the transfusions by forming antibodies were most likely those who would mount a strong immune response against their graft. Although this hypothesis may seem attractive, closer examination shows that it is untenable in cadaver kidney transplants. As discussed previously, the rate at which highly reactive lymphocytotoxic antibodies are formed is low. Even if all highly sensitized patients were excluded, there are too few patients removed by that process to explain the beneficial effect of transfusion upon graft survival.

Since selection cannot be the entire explanation, a more likely reason is that blood transfusions are in some way *actively* inducing a state of immunological unresponsiveness, rendering the host less able to react against foreign histocompatibility antigens. Two possible mechanisms are currently favored: 1) induction of suppressor cells, and 2) induction of anti-idiotypic antibodies.

There is experimental support for the idea that exposure to antigen in the form of blood transfusions must somehow actively induce unresponsiveness. If rodents are exposed to alloantigen on lymphopoietic cells within 24 hours of birth they will become completely tolerant to that antigen and will not mount an immune response against it, even if again exposed to the antigen after they have matured into adults.[7,8] This profound state of unresponsiveness is called neonatal tolerance, and is predicted by the clonal deletion theory. In adult animals, pre-exposure to purified histocompatibility antigens has been shown to be effective in prolonging graft survival in some strain combinations.[9,10] The greatest factor complicating elucidation of the exact mechanism by which pre-exposure of histocompatibility antigens during transfusion works is the high degree of complexity of the MHC. Many minor histocompatibility loci have yet to be defined; consequently their effect is unknown.

Also, it must be remembered that in the normal circumstance the MHC antigens on lymphopoietic cells are directly involved in recognition and communication pathways of the immune response. When these cells are transfused into a recipient, dual recognition of "foreignness" is a likely result with release of different mediators to augment or diminish the immune response of both host and transfused donor cells. Other factors certainly augment the complexity, such as the immune status of the host, the number of cells transfused, timing of transfusions, and degree of compatibility between host and donor cells, just to name a few.

As mentioned previously, two probable mechanisms for the blood transfusion effect have recently gained much attention. A population of T-cells called *suppressor* T-cells have a negative effect on helper T-cells, thereby dampening the immune response. These T-suppressor cells are antigen specific. Therefore, the theory has developed that prior exposure to antigen in the form of blood transfusions somehow augments the proliferation of these cells. Suppressor cells can override the development of cytotoxic T-cells and antibody after organ transplantation. Suppressor T-cell pathways are complex, with different sub-populations and factors involved at the induction phase and the effector phase. Many studies have shown a concommmitent rise in T-suppressor cells in response to blood transfusions, but whether this occurrence is the actual cause of the relative immunological responsiveness is not known.

A second possible mechanism is that blood transfusions will induce *anti-idiotypic* antibodies which will react against T-cell receptors that are specific for histocompatibility antigens of the donor, thereby preventing those cells from recognizing HLA antigens. It has been demonstrated that as the titer of cytotoxic antibody against HLA antigens develops, there is simultaneously a rise in antibody to the idiotype (specific receptor site) of that primary antibody, called anti-idiotype. It is probable that the primary antibody titers diminish because of immune complex formation of anti-idiotype with primary antibody. In addition, the anti-idiotype probably shuts off production of that primary cytotoxic antibody by reacting with the B-cells responsible for producing it. As in the case of T-suppressor cells, the presence of anti-idiotypic antibody has been demonstrated after blood transfusions, but it is not known if these antibodies are the primary agents responsible for the relative unresponsiveness seen in transfused organ transplant recipients.

Immunosuppression

Although prior exposure to histocompatible antigens through blood transfusion was an important advance, none of the dramatic results of organ transplantation in the past 20 years would have been possible without the use of drugs to diminish the immune response. The most important discovery was that by Robert Schwartz, M.D. at Tufts University. He discovered that 6-mercaptopurine could prevent the formation of specific antibody when rabbits were immunized with human serum albumin.[11] Later investigators showed that an analogue of 6-MP, azathioprine, was equally effective and less toxic. When used in combination with corticosteroids, a long term survival of organ transplants was possible.

When used in man, the combination of azathioprine and prednisone has resulted in the successful transplantation of organs between totally histoincompatible individuals. However, in that setting, it is very likely that a certain degree of immunoalteration has also occurred from prior exposure to histocompatible antigens, or by some other means. There is also a phenomenon of "graft adaptation", whereby the recipient and organ enter into an immunologic state that permits graft survival with much lower doses of immunosuppression than would have been possible shortly after the transplant. This phenomenon seems to be in full effect between six months and one year post-transplant. It does not mean, however, that chemical immunosuppression can be discontinued. In most individuals, especially those who have received less well matched cadaver kidney transplants, chemical immunosuppression must be continued throughout the life of the recipient. The dose, however, can be progressively lowered so that side effects from the medications can be minimized.

In the decade between 1965-75, the most important lesson concerning chemical immunosuppression was to lower the dose of corticosteroids at appropriate times. When a rejection episode became evident, that is, a period of detectable heightened immunologic activity which was threatening the survival of the graft, that episode could be reversed with a transient increase in corticosteroids. Intermittant doses of methyprednisolone are especially effective in reversing these transient episodes of rejection activity. The dose of corticosteroids is then progressively lowered to what appears to be a safe dose as far as side effects are concerned, and yet high enough to prevent further rejection episodes. If repeated rejection episodes occur, then the treatment with high dose corticosteroids will be repeated. However, after three such treatments, the likelihood of serious side effects becomes so great that further rejection episodes are rarely treated.

An important recent development is cyclosporine. This chemical produced by a fungus has a unique property in having its primary immunosuppressive effect directed upon helper T-cells. These cells amplify the rejection process and are inhibited by cyclosporine. Cyclosporine in conjuction with either azathioprine, prednisone or possibly low doses of both these drugs has resulted in a 10-20% improvement in survival of cadaver organ transplants. By having a steroid sparing effect, cyclosporine has dramatically decreased the steroid related complications.

An unfortunate side effect of cyclosporine is nephrotoxicity. This makes management of kidney transplantation especially difficult, since differentiation between a rejection episode and cyclosporine toxicity is not always clear. Despite this drawback, cyclosporine has permitted cadaver organ transplantation to a level not seen before. This is obviously very important in heart and liver transplant recipients.

Another immunosuppressive agent used with other drugs is antithymocyte globulin, a globulin preparation from horses or rabbits directed against human lymphocytes. In the case where the material is directed against thymocytes and purified to the globulin preparation, this antithymocyte globulin has a useful role in enhancing the effect of cyclosporine. However, its use must be in great moderation, since the combined effect upon T-cells is such that tumors or serious infections can be induced. In a low dose, or for brief periods of administration, antithymocyte globulin appears to have a useful role in preventing the rejection of organ transplants in patients who have not responded well to high dose corticosteroids.

Another type of biologic preparation that will aid in the reversal or prevention of rejection episodes are monoclonal antibodies. These antibodies, having very high specificity against certain antigens, such as those present on thymus cells, permit a greater degree of selectivity. By not reacting with platelets, polymorphonuclear cells, or red cells, the monoclonal antibody will permit reversal of a rejection episode without having other serious side effects.

A drawback with the use of the monoclonal antibody is that the material is currently prepared in mouse cells. The mouse gammaglobulin is highly immunogenic, resulting in sensitization of the recipient against mouse gammaglobulin. This sensitization does not appear to have a serious effect upon the function of the monoclonal antibody during a first time administration, which usually lasts 10 days. However, subsequent administration may not be effective because of the rapid elimination of the monoclonal antibody by the recipient's anti-mouse antibody.

By now the reader of this paper can certainly appreciate the complexity of immunologic factors in organ transplantation. It is indeed humbling to realize that our knowledge in this area is very likely only in its rudimentary stage. Yet progress in organ transplantation has been rapid—from an impossible dream less than three decades ago to almost routine clinical procedures. Further understanding of the underlying immunologic mechanisms will undoubtedly open new horizons.

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Management of Extracranial Carotid Artery Aneurysms

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ABSTRACT– Extracranial carotid artery aneurysms are rare. Six cases are presented which were treated over a seven year period from 1977 to 1984. There were three fusiform aneurysms, two pseudoaneurysms, and one saccular aneurysm.

The mode of presentation varied greatly. Multiple surgical techniques for extracranial carotid artery aneurysm resection and reconstruction are described and the need for intra-operative temporary internal carotid artery shunting is emphasized.

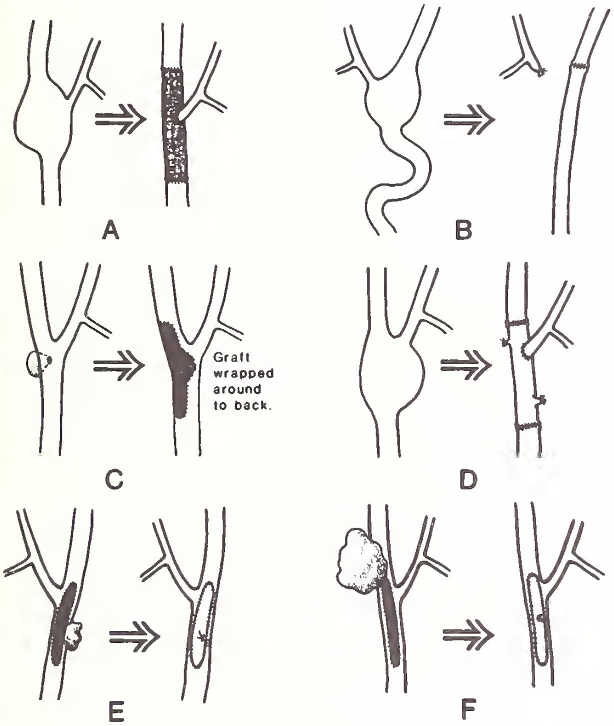

Figure 1
Diagram of Various Operative Reconstructions
A. PTFE graft with external carotid artery implantation
B. End-to-End anastomosis with external carotid artery ligation
C. PTFE patch angioplasty
D. Saphenous vein graft with external carotid artery implantation
E. Excision of dacron patch with saphenous vein patch angioplasty
F. Excision of dacron patch with saphenous vein patch angioplasty

Aneurysms of the extracranial carotid artery are rare.[1-3] The History of treatment of these lesions dates back to the first proximal ligation of a cervical carotid aneurysm in 1805 by Sir Astley Cooper.[4] Nathan Winslow compiled 106 cases of extracranial carotid aneurysms in 1925 and reported a 70% mortality without treatment and a 30% mortality with surgical ligation of the common carotid or internal carotid arteries.[3] He re-emphasized the role of ligation in these patients in expansion of his series in 1936.[5] This remained the standard care until Kirby's attempt at restoration of arterial continuity in 1949[6] and the first successful reanastomosis after carotid aneurysm resection by Dimtza in 1956.[7] With the advent of modern vascular surgical techniques, aneurysmorrhaphy or resection with reconstruction of the carotid artery has become the treatment of choice.[8-10]

Six cases of carotid artery aneurysm were treated at Hartford Hospital over a seven year period (1977-1984).

Case Reports

Case 1: A 62-year-old man presented with a right hemispheric cerebral vascular accident. Over four weeks, his neurologic deficit improved and he then underwent carotid angiography which showed a 2.0 cm fusiform aneurysm of the right carotid bifurcation. He underwent resection of the aneurysm and carotid artery reconstruction with a temporary silastic shunt threaded through a polytetraflouroethylene (PTFE) interposition graft. The external carotid artery was implanted into the PTFE graft. (Figure 1a) The patient did not suffer any complications.

Case 2: A 71-year-old man presented with a pulsatile mass in his left neck. Ultrasound evaluation showed a 2.0 cm fusiform aneurysm of the carotid bifurcation and carotid angiogram confirmed this diagnosis and also showed a tortuous common carotid artery. The aneurysm was resected and the external carotid artery was ligated. Because of the redundancy of the common carotid artery, a primary end-to-end anastomosis was performed of the common carotid artery to the internal carotid artery over a silastic shunt. (Figure 1b) No post-operative complications occurred.

Case 3: A 68-year-old man presented with right eye amaurosis fugax. Carotid angiogram showed a 90% right internal carotid stenosis but no aneurysm. On exploration he was found to have a 1.0cm. saccular aneurysm protruding from the posterior aspect of the carotid bifurcation. He underwent endarterectomy and resection of the aneurysm with PTFE patch reconstruction of the defect with a temporary silastic shunt. (Figure 1c) There were no complications.

Case 4: A 32-year-old man with a history of Takayasu's Arteritis presented with right eye amaurosis fugax. Angiogram showed complete occlusion of the left common carotid artery and a 2.0cm. fusiform aneursym of the right carotid bifurcation. He underwent resection of the aneurysm with a reversed saphenous vein interposition graft mounted over a silastic shunt. The external carotid artery was implanted into the side of the graft. (Figure 1d) He tolerated the procedure well.

Case 5: A 66-year-old woman presented six years after left carotid endarterectomy with drainage from her old incision. She had had intermittent drainage from the wound over the six years and had undergone multiple courses of antibiotics as well as two drainage procedures for superficial abscesses. Angiogram was performed at this time showing a 0.7 cm pseudoaneurysm. At exploration she had a 7.0 cm pseudoaneurysm arising from the middle of the posterior suture line. The entire dacron patch was excised and the carotid artery was reconstructed

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with a saphenous vein patch over a temporary silastic shunt. (Figure 1e) Wound cultures were sterile and the patient recovered without any complications.

Case 6: An 81-year-old man presented 15 years after right carotid endarterectomy with dacron patch reconstruction. He had a large pulsatile mass in his right neck with an audible bruit. Computed Tomography showed a 4.3 cm x 3.3 cm pseudoaneurysm arising at the carotid bifurcation with laminated clot in the lumen. Angiogram corroborated this finding. At operation the pseudoaneurysm was found to be arising from the distal end of the dacron patch. The patch was excised and the carotid was reconstructed with a saphenous vein patch without any shunt. (Figure 1f) There were no complications.

Clinical Data

There were three fusiform aneurysms, two pseudoaneurysms, and one saccular aneurysm in this series. The two pseudoaneurysms arose along dacron patch suture lines. Five of the aneurysms were located at the carotid bifurcation. One was lower in the common carotid artery. The aneurysms ranged in size from 0.7cm. to 4.2cm. There were five males and one female. The median age was 67 (range:32-81).

The modes of presentation are listed in Table 1. The diagnosis of carotid artery aneurysm was made correctly by ultrasound in one patient and computed tomography in another patient. Carotid angiography was performed in all six patients pre-operatively and demonstrated the aneurysm in five (83%).

Table 1

Signs & Symptoms	*# of Patients*
Amaurosis Fugax	2
Pulsatile Mass	2
Cerebral Vascular Accident	1
Drainage	1
Bruit	1

Treatment

The operations were all performed under general anesthesia. Internal carotid artery flow was re-established in all six cases. A temporary silastic shunt was used to maintain internal carotid artery perfusion in five of the six patients.

Operative management of the two pseudoaneurysms consisted of excision of the dacron patch and autogenous saphenous vein patch reconstruction. Reconstruction of the other carotid arteries after aneurysmectomy was accomplished by a variety of methods: primary end-to-end anastomosis of the common carotid artery to the internal carotid artery; endarterectomy and aneurysmectomy with PTFE patch reconstruction; reversed autogenous saphenous vein graft interposition with implantation of the external carotid artery into the graft; and PTFE interposition graft with implantation of the external carotid artery into the graft. (Figure 1) There were no deaths, neurologic complications or local wound complications.

Discussion

Carotid artery aneurysms can present with a variety of symptoms. (Table 1) An asymptomatic pulsatile mass is the most common presenting complaint in most series. The differential diagnosis includes tortuous normal caliber vessels, carotid body tumors, cervical lymphadenopathy, and even peritonsillar abscesses. Pseudoaneurysms are a possibility in any patient with a history of pervious carotid surgery and are four times as common following dacron patch angioplasty as compared to endarterectomy alone.[2]

Ultrasound and computed tomography studies can be helpful in differentiating carotid artery aneurysms from these other lesions, especially tortuous normal caliber carotid or subclavian arteries.[1] Pre-operative angiography for anatomic definition is mandatory but may not show the aneurysm because of laminated clot in the lumen.

Most aneurysms are confined to the common carotid artery bifurcation or the accessible internal carotid artery.[1] Mandibular subluxation has been described as a method of increasing distal exposure and accessibility of distal internal carotid artery aneurysms.[12] Thus, in most cases, the surgeon has the option for reconstructive treatment to avoid the high incidence of cerebral vascular accidents and mortality associated with simple ligation of carotid artery aneurysms.[3,11]

Most often the aneurysm is not hemodynamically significant and the patient has not developed a good collateral circulatory network. Therefore, internal carotid artery perfusion should be maintained with a shunt throughout any operative procedure as failure to do so has been reported to have an unacceptable 25% - 29% incidence of stroke.[11,13] Reconstructive conduits of saphenous vein of PTFE can be threaded over the shunt prior to its placement.

The exact surgical method of reconstructive technique which is used in a given case must be individualized. We have described our six cases which were all treated differently. These surgical techniques have applicability to the reconstruction of some carotid endarterectomies with thinning or destruction of the adventitia and carotid body tumor resections as well as carotid artery aneurysm resections.

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Continuous Catheter Irrigation for the Treatment of Suppurative Flexor Tenosynovitis

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ABSTRACT— A comparison of the technique of continuous catheter irrigation versus wide incision and drainage for the treatment of suppurative flexor tenosynovitis was performed via a retrospective analysis of 17 patients with documented flexor tenosynovitis. Nine patients underwent unilateral or bilateral mid-axial sheath incisions with open packing, and eight were treated with a continuous catheter suction-irrigation system. The groups were compared with regard to length of stay, re-infection, subsequent procedures, re-hospitalization and functional results. Continuous catheter irrigation was found to provide rapid elimination of infection, decreased length of stay, decreased incidence of re-infection, fewer subsequent procedures and hospitalizations, and more rapid and complete return of function.

Introduction

Suppurative flexor tenosynovitis is an infection involving the flexor sheath and its contents including the flexor tendon, vincula and synovial fluid. The etiology of suppurative tenosynovitis is usually traumatic, resulting in a break in the skin's integrity over the volar or lateral aspect of the finger. Due to the close proximity of the flexor sheath and volar skin, contiguous spread of infection can occur quite easily. With the advent of improved techniques of initial wound care, including copious irrigation and prophylactic antibiotics when indicated, as well as the use of antibiotics early in cases of cellulitis or contiguous infection, suppurative tenosynovitis has become an uncommon entity. However, once an infection has spread to the tendon sheath, it is a surgical emergency.

Unfortunately, suppurative tenosynovitis is often diagnosed late or initially managed with non-surgical means such as soaks and antibiotics. Treatment of suppurative tenosynovitis must be undertaken rapidly with the surgeon's goals being rapid elimination of the infection with preservation of hand function and minimizing patient inconvenience and cost.

Anatomy

Each tendon is enclosed within a fibro-osseous tunnel, with the phalanges and joints making up the dorsal boundaries and the firm, ligamentous pulley systems and fragile synovial sheath forming the volar and lateral boundaries. This tunnel is a fairly unyielding structure that cannot allow for the rapid swelling that occurs with tenosynovitis. Consequently, as pressure within the sheath arises, tendon ischemia and necrosis rapidly ensue. In addition to this, bacterial and lysosomal enzymes, released in the presence of infection, caused marked tendon damage. The thumb and little finger sheaths often communicate with the radial and ulnar bursae, which may provide some temporary decompression for sheath infection of the thumb and little finger. The remaining sheaths, if ruptured, may extend into the palmar spaces causing a devastating hand infection.

The central portion of the tendon receives most of its blood supply via the vincular system, the vincula longa and brevis. The tendon is lubricated by synovial fluid which is produced from the lining of the tendon sheath. Synovial fluid enables the tendon to glide smoothly within the sheath and has been shown to play a significant role in tendon healing and as a nutritional support for the super-

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ficial layers of the tendon and portions of the tendon that are not in close proximity to the vincula.[1]

Diagnosis

The clinical signs of suppurative tenosynovitis described by Kanavel are quite classic. The patient presents with a painful swollen finger which may have a very rapid onset of as little as eight hours. The entire finger is swollen along its volar and lateral aspects and held immobile in a semi-flexed position. There is marked tenderness along the tendon sheath, especially at the cul de sac, and extreme pain is elicited with attempted passive motion. The patient may be febrile and occasionally has an elevated WBC, ESR, and lymphadenopathy; although in many cases, the findings are limited to the hand.

It has been well established that true suppurative tenosynovitis should be treated surgically.[2,4-6,8,10,11,13] However, many hand infections are treated initially with elevation and antibiotics. Treatment has varied in the past from removing the entire involved tendon,[3] sheath excision,[2] unilateral or bilateral sheath incisions with open packing and drains,[2,4,6-8] aspiration and injection of antibiotics,[4] and additional palmar incisions over the cul de sac and radial or ulnar bursae.[8] Catheter irrigation of tendon sheath infections was first performed by Sir Dickson Wright[10] in 1943 who described placing a ureteric catheter into the tendon sheath, and flushing with saline intraoperatively. This was followed by daily instillation of one to two cc's of a dilute penicillin solution for up to seven days. Murray[5] in 1951 compared the methods of I & D versus sheath irrigation and found that patients treated with irrigation made a rapid recovery with more complete return of function. Carter[11] in 1966 described a method of intraoperative tendon sheath irrigation with an indwelling catheter through which hydrogen peroxide followed by a dilute solution of oxytetracycline was flushed. In severe cases, the catheter was advanced well into the sheath and a continuous drip of antibiotic solution was run for one to two days. Neviaser[13] in 1978 reported the use of an indwelling catheter and a penrose drain, with manual flushing of 50 cc's of normal saline every two hours for one to two days.

Materials and Methods

A comparison of the technique of continuous catheter irrigation versus wide incision and drainage in the treatment of suppurative flexor tenosynovitis was performed via a five year retrospective analysis of 17 patients with documented flexor tenosynovitis. In each case, the treatment method was chosen per the surgeon's preference. The irrigation method was employed by three orthopaedic surgeons who were familiar with this technique. None of the patients were diabetic, and, from the available descriptions, the cases were of comparable severity.

Nine patients underwent unilateral or bilateral mid-axial sheath incisions with open packing, and eight were treated with a continuous catheter suction irrigation system. In the irrigation group, the mean age was 31.9 years with a range of 4 to 55. In the I & D group, the mean age was 37.3 with a range of 13 to 62. In all but one case, the etiology of tenosynovitis was traumatic, with one case resulting from a postoperative wound infection in a patient who underwent delayed repair of a severed flexor tendon and digital nerve. The average length of time from injury to surgical intervention was 5 days in the irrigation group, and 4 days in the I & D group. Staph aureus was the predominant infecting organism. In addition, bacteroides, acinetobacter, and streptococcus were found in combination with staph in three separate instances.

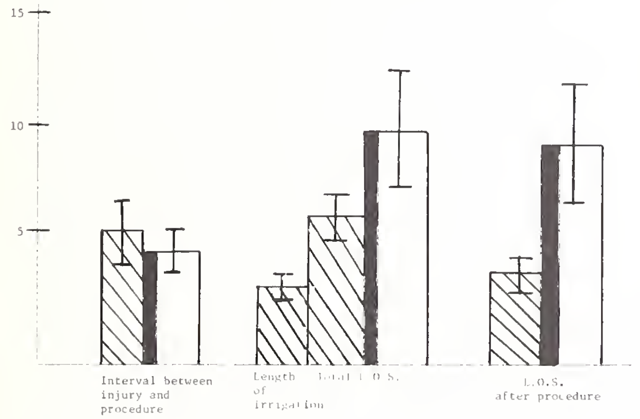
Technique

The I & D method was performed via single or bilateral mid axial incisions extending into the tendon sheath. In five cases, the wound was packed open with petroleum gauze or penrose drains, and in the remaining four, the wounds were left open and treated with warm soaks and gauze packing. The method of catheter irrigation employed was the same in all eight cases. This technique, developed by H. K. Watson, is a modification of the previously described methods of sheath irrigation. It employs small chevron incisions, one in the palm over the proximal sheath, and, one over the DIP joint.

The sheath is entered and a 16-gauge catheter which has been prepared with multiple perforations is carefully threaded through the entire sheath. The catheter is then connected to a suction irrigation system with an inflow of lactated Ringer's at 40 cc/hour and high wall suction as the outflow. This method differs from those in the literature in that it is a continuous suction irrigation system that remains patent. Past experience with continuous flow systems, using a gravity drip inflow and a penrose drain as the outflow, have been unsuccessful since the system occludes after a short time.[11,13] Following placement of the catheter, the hand is immobilized in the position of function in a bulky hand dressing and plaster splint. The system is run for at least two days, allowing continuous mechanical debridement. The system has run successfully for up to seven days. The outflow solution clears within three hours of starting the flow, and has been found to be sterile by 12 to 24 hours.

Results

Figure 1 shows a comparison of the two groups with regard to the interval between injury and surgery, total length of stay, length of the irrigation period, and length of stay following the surgical procedure. The interval between injury and surgery was 4 days in the I & D group and 5 days in the irrigation group. The total length of stay was 10.2 days in the I & D group and 5.75 days for the patients treated with irrigation. The average period of continuous irrigation was 2.75 days. We analyzed the data in a different way to look at the length of stay following the procedure and found that, in the irrigation group, the length of stay following the procedure very closely paralleled the period of irrigation. Therefore, the irrigation technique resulted in a more expedient discharge from the hospital. In the I & D group, however, there was no significant difference in length of stay following the procedure compared with total length of stay. Complications encountered are depicted in Figure 2. These include re-infection, repeat drainage procedures, delayed reconstructive surgery, and repeat hospitalizations. One patient in the irrigation group had suffered a human bite injury seven days prior to admission and had been treated with irrigation for 48 hours and discharged. The patient was non-complaint with maintaining a clean, dry dressing, and returned one week later with re-infection requiring a repeat irrigation procedure. This was run for seven days with complete resolution. In the I & D group, four patients had repeat infections requiring re-hospitalization for repeat I & D and antibiotics. One patient in the irrigation group required delayed free tendon grafting. He had developed tenosynovitis as a postoperative wound infection following delayed repair of a severed flexor tendon and digital nerve. In the I & D group, seven reconstructive procedures were performed on five patients, including 2 neurolyses, 2 tenolyses, 1 capsular release, 1 arthrodesis, and 1 amputation. With regard to subsequent admissions, 2 patients in the irrigation group required re-hospitalization and complications in 6 patients in the I & D group resulted in 8 re-hospitalizations.



	Mean Age	Range
Irrigation	31.9	4-55
I & D	37.3	13-62

Figure 1

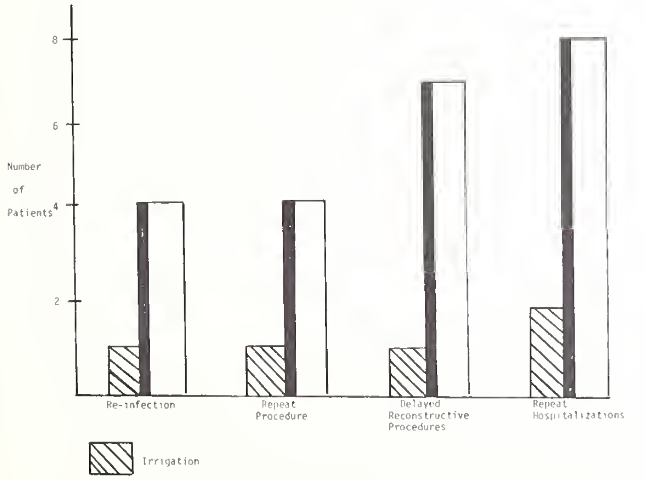


Figure 2

Functional results obtained with the continuous irrigation were quite good. In Table 1, 4 out of the 8 patients regained complete ranges of active and passive motion. Three patients were categorized as having a good result with lacking 20-40 degrees of total active motion. The one case that resulted in a poor outcome was the patient who had developed tenosynovitis secondary to a postoperative wound infection resulting from a delayed repair of a severed flexon tendon and digital nerve. He went on to develop tendon necrosis and has subsequently required delayed free tendon grafting. Among the I & D group, there were no excellent results. Two patients were judged as having good results; three had a fair result which was categorized as lacking 40-60 degrees of total active motion. There were two patients with poor results which was defined as lacking 60 or more degrees of total active motion. One patient required an amputation of the digit secondary to osteomyelitis and tendon necrosis, and one patient required arthrodesis secondary to complete instability of the PIP joint.

Table 1

Results	*I&D*	*Irrigation*
Excellent	0	4
Good	2	3
Fair	3	0
Poor	2	1
Amputation	1	0
Arthrodesis	1	0
Total	9	8

Discussion

It has been well documented that suppurative tenosynovitis should be treated surgically. Various methods of incision and drainage that involve filleting the sheath with open packing are unsatisfactory for several reasons. The commonly used mid-axial incision jeopardizes the dorsal branches of the digital nerve which lie directly beneath this incision. It also exposes the neurovascular bundles and lateral bands to the infecting organisms and mediators of inflammation, and transforms an infection that is contained within the confines of the tendon sheath into a disseminated one. In this series, the patients treated with I & D had a higher incidence of re-infection, re-hospitalization, and subsequent delayed reconstructive surgery. They suffered greater disability secondary to incomplete return of function, arthrodesis, and amputation. This particular method of continuous catheter irrigation provides a rapid elimination of the infection, decreased length of stay, decreased incidence of re-infection, fewer resultant complications and subsequent procedures, and more rapid and complete return of function. As mentioned, this method of continuous catheter irrigation differs from those described in the past in that it is a continuous suction irrigation system with a perforated catheter that runs the entire length of the tendon sheath. Using this method, we have had great success in maintaining the continuous system for as long as seven days, avoiding the problem of outflow catheter obstruction.

Catheter irrigation as a means of treatment for suppurative tenosynovitis which utilizes limited synovial sheath incisions and mechanical lavage, maintains the integrity of the tendon sheath, thereby avoiding the possible complications of neurovascular involvement and adhesion formation. By preserving the tendon sheath, the synovial environment is preserved which allows for rapid tendon healing and return of function.

This method of catheter irrigation is presented as a simple, closed, continuous system that can be easily employed. It avoids the problem of outflow obstruction, sheath inflation, and wet dressings. It is a continuous, sterile system which negates the need for manual sheath irrigations postoperatively, decreasing the risk of contaminating the irrigation tubing. As with other forms of catheter irrigation, this method was found to provide rapid elimination of infection, few subsequent procedures and hospitalizations, and rapid, more complete return of function.

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A Comparison of Steroid and Thiazide Diabetes

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ABSTRACT— Many drugs have been associated with exacerbating apparent or latent diabetes mellitus. Two drugs frequently implicated are adrenalcorticosteroids and thiazide diuretics. I recently treated two particularly well documented cases related to useage of these agents, illustrating the comparative features of these problems.

Case Report

Case No. 1: A 69-year-old, 83 kg. white male was admitted with polyuria, polydypsia, weight loss and hyperglycemia. From 1977 through 1984, the patient had annual 4 p.m. glucoses between 107 and 137 mg./dl. There was no family history of diabetes. In March 1985, the patient was admitted severely anemic with autoimmune Coomb's positive hemolysis. Random glucose on admission was 269 (Figure 1). Subsequent random glucoses ranged from 133 to 155. On March 20, the patient was started on 60 mg. per day of Prednisone. His anemia stabilized and he was discharged nine days later on 55 mg. of Prednisone. On April 12, the patient developed the hyperglycemic symptoms and one week later presented with a glucose of 532 mg./dl. without acidosis. He was treated with NPH insulin and was relatively insulin resistant requiring 65 units a day by the 5th hospital day with a 4:00 p.m. glucose of 300. His Prednisone was reduced from 55 to 42.5 mg. per day during the admission. He was discharged on April 26, 1985 on 50 units of NPH with a glucose of 229. His Prednisone was tapered as an outpatient at 2.5 mg. per week. His blood sugar remained in reasonable control on reducing doses of insulin. In November, 1985, off Prednisone and Insulin, his 4:00 p.m. glucose was 161.

Case No. 2: A 50-year-old black 70 kg. female presented with hyperglcemia and with a three week history of polyuria, polydypsia, and polyphagia. In 1977, the patient had random glucoses of 90 and 80 mg./dl. (Figure 2), In November 1977, she was placed on hydrochlorothiazide 50 mg. per day for hypertension. Random glucoses

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6 and 12 months later were 90. Eighteen months after starting hydrochlorothiazide, the patient was admitted with a random glucose of 675 without ketosis. Her hydrochlorothiazide was discontinued and she was started on insulin. Her blood sugars quickly returned to normal and she was discharged off insulin with a normal blood sugar. A few weeks after discharge she was restarted on hydrochlorothiazide by another physician and two weeks later presented with a blood sugar of 320 and diabetic symptoms. Her hydrochlorothiazide was discontinued again and she was started on insulin a second time. She discontinued the insulin in early 1980. Random glucoses subsequently ranged from 70 to 130 over the next 3 years, including 84 in October, 1983. In September 1984, the patient was started on hydrochlorothiazide 50 mg. for hypertension. In March of 1984, the patient developed hyperglycemic symptoms and three weeks later presented with a glucose of 654. She was started on human insulin and the hydrochlorothiazide was discontinued. She was eventually controlled on 65 units of human insulin per day and was discharged with a glucose of 100. Six days post discharge on April 21, the patient discontinued her insulin. On April 26, a random glucose was 121. Subsequently, the patient had an abnormal glucose tolerance test with an FBS of 173, 1 hour post parandial, 231; two hour post parandial, 346; and three hour post parandial, 370. Most recent random blood sugar was 109.

Figure 1

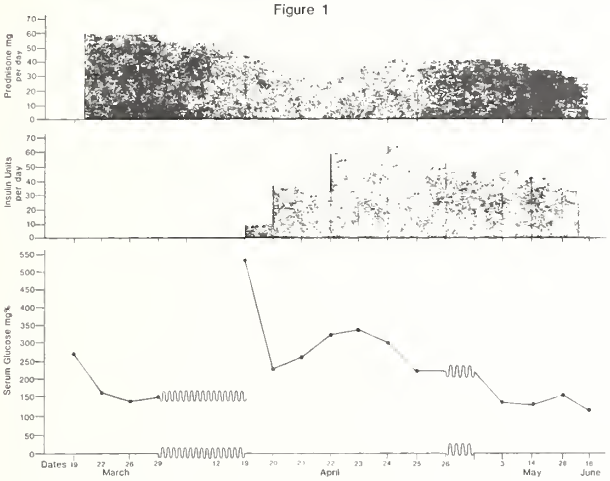
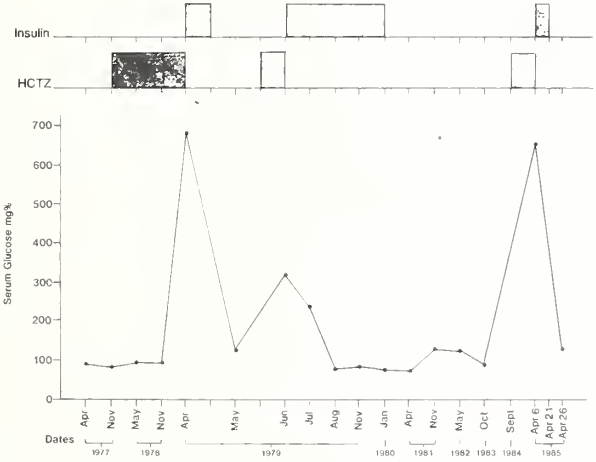


Figure 2



Discussion

Case 1 was a 68-year-old moderately obese male without a family history of diabetes but with documented prior random glucose elevations, who developed relatively severe hyperglycemia without ketosis 3 weeks after starting high dose cortiosteroids. His diabetes was relatively insulin resistant. As the steroids were reduced, his diabetic control improved despite the decreasing doses of insulin.

Shortly after the introduction of exogenous glucocorticoids for clinical use, Bookman, et. al.,[1] in 1953, reported 5 patients in a rheumatology clinic who developed hyperglycemia following the use of glucocorticoids. The maximum glucose in these cases was 290 mg. per dl. Four of these patients had a positive family history of diabetes. One had prior glucosuria. The authors also noted that these patients were relatively insulin insensitive; that the diabetes was dose related; and that it was reversible with cessation of steroids. Based on a rough estimate of the clinic population, the authors concluded that the incidence of steroid diabetes was less than one per cent of patients taking corticosteroids.

Since these observations, there have been some refinements in our knowledge of the incidence of steroid diabetes; its severity, including the potential for development of hyperosmolar state and ketosis; and risk factors for development. Woods, et. al.,[2] noted a 5.5% incidence of steroid diabetes in patients followed over a period of 10 years on a renal transplant service. Seven of the 11 affected patients had a positive family history. Three presented with hyperosmolar non-ketotic coma. Not only was the hyperglycemia severe in some patients but also developed very rapidly, one day to four months after initiation of steroids. David, et. al.[3] reported a 10.8% incidence in a renal transplant population. The higher incidence in this series compared to previous reports probably related to a stricter definition of diabetes. The authors also noted a higher incidence among blacks, the elderly and in HLA-28 antigen positive individuals.

Ketosis in steroid diabetes has been described. Alavi, et. al.[4] reported 5 patients who developed significant ketoacidosis while receiving high dose steroids for prolonged periods for rheumatic diseases. Four patients had received 60 mgms. of prednisone and one 30 mgms. of prednisone daily with a minimum interval of 2 months and a maximum of 8 months following the initiation of therapy.

The mechanism of steroid diabetes apparently is related to its impact on gluconeogenesis and also possibly to direct insulin antagonism peripherally.

The second patient experienced three separate episodes of documented nonketotic hyperglycemia, two with glucoses of over 600. All three episodes occurred while on hydrochlorothiazide, 18, 1, and 6 months after starting the drug. The most recent episode was relatively insulin resistant. In all three instances, the patient became normoglycemic after discontinuing the hydrochlorothiazide.

Thiazide diuretics became available in 1957. In 1960, Goldner, et. al.,[5] reported a patient with prior normal glucoses but with a positive family history who developed diabetes (glucose 476) one month after starting chlorthiazide. The thiazide was discontinued and the patient's blood sugar returned to normal. The authors subsequently studied 20 diabetic and 20 non-diabetic patients. They gave each patient thiazide diuretics, and found no difference in glucose tolerance in the non-diabetic group. However, in 6 (30%) of the diabetic population, there was worsening of glucose tolerance. This effect was not related to potassium levels, and was reversed when the thiazide was discontinued. The authors concluded that thiazides can worsen existing diabetes mellitus, the drug can bring out latent diabetes in predisposed patients, the diabetes is reversible with cessation of the drug, the degree of hyperglycemia is not related to hypokalemia, and the hyperglycemia was usually mild.

Since Goldner's article, there have been numerous studies of thiazide related diabetes. However, because of conflicting data in a number of epidemiological studies, doubts have persisted regarding the seriousness of this problem and even its existence. Bergland and Andersson[6] followed 53 hypertensive patients on thiazides for 6 years and found no increase in blood glucoses in all but one patient. Murphy, et. al.[7] studied 34 patients for 14 years. They found no change in blood sugars after 1 year on thiazides; a small decrease in glucose tolerance after 6 years; and more severe hyperglycemia at 14 years. Current epidemiologic data, including that published in the Hypertension Detection and Follow Up Program,[8] supports the relationship of diuretics to development of symptomatic hyperglycemia but at a low level. In the latter study 1.6% of patients were forced to discontinue chlorothalidone because of the development of diabetes. Thus, although strong evidence of a causal relationship is lacking, available studies and reports in toto support a relationship between thiazides and diabetes.

The degree of hyperglycemia that develops on thiazides is generally mild. Of 25 patients who developed thiazide diabetes in a large Swedish study,[9] only 2 had blood glucoses greater than 200 mg/dl and required insulin. While there have been isolated reports of hyperosmolar states developing after treatment with thiazides,[10,11] ketoacidosis has not been reported. This patient's severe hyperglycemia on two occasions following thiazide intake points out the potential seriousness of the problem in selected individuals.

Although Goldner[5] concluded that thiazide induced hyperglycemia was not related to hypokalemia, a number of subsequent reports supported this etiologic relationship. However, the question remains unresolved in light of other studies that failed to demonstrate a correlation between serum potassium and/or total body potassium with the development or severity of hyperglycemia.[12,13] Hypokalemia may indeed be a factor but probably only a contributory one. Other possible mechanisms of thiazide induced hyperglycemia include peripheral antagonism of insulin or pancreatic toxicity.

The relationship of glucose intolerance to administration of the steroids and thiazide diuretics was demonstrated exceptionally clearly by these two patients. In context of the literature, one can make the following comparison (Table 1).

Table 1

COMPARISON OF THIAZIDE AND STEROID DIABETES

	Thiazide Diabetes	*Steroid Diabetes*
Approximate incidence of clinically significant disease	1 - 2%	5 - 10%
Occurs in predisposed patients predominately	yes	yes
Interval after initiation of drug	2 weeks - 14 years	days to months
Severity	mild, rarely severe	mold, occasionally severe
Potential for development of hyperosmolar state	yes	yes
Potential for development of ketosis	not reported	yes
Dose relationship	not applicable	yes
Reversibility	yes	yes
Relative insulin resistance	uncertain	yes
Mechanisms	unknown, potassium possibly a factor	probable peripheral insulin antagonism and/or gluconeogenesis

Steroid diabetes occurs in approximately 5 to 10% of patients who take the drug. It is most likely to occur in patients who have a positive family history or are otherwise predisposed. The interval between initiation of drug and development of diabetes can be as short as several days, or as long as several months. If a patient has not developed steroid diabetes within the first year of taking the drug, he is unlikely to develop it later. Steroid diabetes tends to be mild but is occasionally severe and can present as hyperosmolar nonketotic coma as well as ketoacidosis. Glycemic control is difficult while patients remain on steroids but is improved with reduction in dosage. The diabetes is reversible. Steroid diabetic patients tend to be relatively insulin resistant. The mechanism for steroid diabetes is probably peripheral insulin antagonism and/or gluconeogenesis.

Thiazide diabetes occurs less frequently, in approximately 1 to 2% of patients taking thiazides. It is also most likely to occur in patients predisposed to develop diabetes. The interval after initiation of drug is not as predictable as in steroid diabetes, and can be weeks or greater than a year, as in our case. Thiazide diabetes is likely to be mild but rarely can be more severe, as in our case. Hyperosmolar states have been reported, but ketoacidosis has not. No relationship between dose of thiazide and hyperglycemia has been shown. Like steroid diabetes, thiazide diabetes is likely to be reversible. Insulin resistance is unclear since so few patients take insulin for the disease. Although the mechanism for thiazide diabetes is uncertain, hypokalemia may be a contributory factor.

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IN AN OPEN LETTER to the leadership of organized medicine, the AMA Board of Trustees has appealed for all physicians to continue to accept Medicare assignment wherever warranted by financial circumstances of patients. The board also has asked medical societies to demonstrate the profession's concern for the economically deprived by either developing or spurring the development of local programs that enable low-income Medicare beneficiaries to receive all their care on an assignment basis.

Here is the text of the board's open letter, dated June 18, 1986, that was distributed at the Annual Meeting:

"Organized medicine is in the forefront of providing cost effective medical care. Physicians have a long tradition of providing medical care to patients in every economic situation. Medical societies are also typically involved in many activities to help patients in the local communities.

"In concert with these commitments the Board of Trustees and officers of the American Medical Association are asking physicians to continue to accept assignment for Medicare beneficiaries whose economic situation dictates the need for this type of assistance. Beneficiaries who can afford it can continue to pay the full cost of the physician's service.

"In addition, the AMA is asking that medical societies take the lead in programs at the local level to help provide assignment for all low-income beneficiaries. It is important as we negotiate with leaders in the Administration, Congress, and beneficiary groups to show that medical groups continue their vigorous programs for low-income beneficiaries."

— AMA Newsletter, Vol. 18, No. 22, 1986

Important Advances in Clinical Medicine

Epitomes of Progress—Nuclear Medicine

The Scientific Board of the California Medical Association presents the following inventory of items of progress in nuclear medicine. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in nuclear medicine that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Nuclear Medicine of the California Medical Association and the summaries were prepared under its direction.

Radionuclide Scrotal Imaging

A relatively abrupt onset of painful swelling of the scrotal contents is commonly caused by either torsion of the spermatic cord or epididymo-orchitis. Torsion requires prompt restoration of blood flow, usually by surgical means, to salvage the compromised testis. Bilateral orchiopexy is also indicated to provide anchorage of the testes to the scrotum. Epididymo-orchitis usually responds to antibiotic therapy. The surgical salvage rate of about 50% in torsion depends greatly on the degree of ischemia and the time elapsed between onset and correction of the ischemia.

Radionuclide scrotal imaging provides a rapid cost-effective means of accurately distinguishing between an essentially avascular process, such as spermatic cord torsion, and a hyperemic process such as epididymo-orchitis. In several combined series, the sensitivity of properly done radionuclide scrotal imaging for detecting acute spermatic cord torsion is 93% or greater, which exceeds clinical sensivity. Most likely to be missed by this technique are torsion in the newborn period and so-called missed torsion in which prolonged ischemia of more than 24 hours' duration has provoked hyperemia in the surrounding scrotum. In most cases, the testis undergoes infarction.

Other processes such as hydrocele, hernia, hematoma and testicular necrosis from a variety of causes appear avascular and can mimic the appearance of spermatic cord torsion. Nevertheless, the specificity of the technique is also high, enabling the diagnosis of torsion of the spermatic cord to be excluded in 93% of other conditions. This spares a patient an unnecessary surgical procedure and expense. The technique is less useful for distinguishing causes of nonacute scrotal masses that may be better sorted out by methods, such as ultrasonography, which characterize tissue densities.

Radionuclide scrotal imaging commonly shows ischemia of the involved testis in men with infertility due to varicocele. Another approach, that of imaging of the blood pool of the scrotal contents with the patient's erythrocytes labeled with technetium 99m, has proved more useful in identifying the varicocele itself. In some cases this technique will define subclinical varicoceles. A similar approach has been used with good results to separate impotence due to vascular insufficiency from other causes.

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Multiple-Gated Equilibrium Radionuclide Ventriculography to Assess Heart Function

Multiple-gated equilibrium radionuclide ventriculography is a relatively noninvasive method for evaluating global and regional right and left ventricular function. Erythrocytes are labeled with technetium 99m. A patient's electrocardiogram is recorded while labeled blood in the right and left ventricles is imaged in at least three projections—such as anterior, 30° to 40° left anterior oblique and left lateral—using a standard gamma scintillation camera. The cardiac cycle is divided into 16 to 32 equal time frames which are displayed in a movie format. Left ventricular ejection fractions are calculated from the left anterior oblique view and correlate well with those by contrast ventriculography. Additional indices obtained with this technique include left ventricular volumes, indices of systolic function, such as first-third ejection fraction and average or peak ejection rate, indices of diastolic function, such as peak filling rate and the time to peak filling rate, and the temporal sequence of ventricular wall motion by phase analysis, which aids in assessing asynchrony of wall motion and of conduction abnormalities. Right ventricular function can be assessed most accurately by gated imaging of a radionuclide bolus transit through the right side of the heart.

This test provides useful information in a variety of clinical situations. Evaluation of right ventricular function at rest is helpful in patients with diseases such as right ventricular infarction, obstructive lung disease, pulmonary hypertension, right-sided valvular heart disease and congenital anomalies. Evaluation of global and regional left ventricular function at rest can provide baseline information in patients with cardiomyopathies and valvular and congenital disease, and aids in monitoring results of surgical procedures and of intravenously given drugs, including the cardiotoxic effects of chemotherapeutic agents, such as doxorubicin (adriamycin) hydrochloride. In addition, prognostic information can be obtained in patients with acute myocardial infarction. Detection of tricuspid regurgitation and of anatomic abnormalities such as true or false left ventricular aneurysm, left ventricular thrombus, atrial myxoma and aortic coarctation is also possible.

Comparison of left ventricular function at rest and during upright or supine bicycle exercise is highly sensitive in diagnosing significant coronary artery disease, enables evaluation of functional reserve in myocardial and valvular disease and may aid in optimum timing of surgical intervention in patients with valvular disease. The response to exercise in men is considered abnormal if any or all of the following occur: the global ejection fraction increases less than 0.05 ejection fraction units, end-systolic volumes increase or fail to decrease or there are new wall motion abnormalities. Healthy women may respond to exercise without the ejection fraction increasing due to an increase in end-diastolic counts. Therefore, an abnormal response would consist of no change or a decrease in ejection fraction.

Exercise equilibrium radionuclide ventriculography is especially useful for detecting coronary artery disease; the sensitivity approaches 90%, although the specificity is only about 60%. This test is most helpful diagnostically in patients with a moderate probability of disease. In this patient population, an abnormal response makes the presence of coronary artery disease highly likely, whereas a normal response lowers the likelihood of significant disease. Therefore, normal results of an exercise test may lessen the need for proceeding immediately with invasive techniques such as coronary arteriography. Finally, the pattern of response to graded exercise aids in estimating the extent and severity of coronary artery disease. In summary, this relatively noninvasive radionuclide test is easy to do and provides highly useful diagnostic and prognostic information.

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Leukocyte Imaging for Detecting Acute Inflammatory Processes

Indium 111-labeled leukocytes are widely used to diagnose acute inflammatory processes. Since its introduction nearly a decade ago, leukocyte scintigraphy has proved to be sensitive, specific and technically feasible for most nuclear medicine departments. In the past three years the indications, potential pitfalls and optimization of the study have been more clearly defined.

Leukocyte imaging has proved most effective in cases of acute inflammatory processes and abscesses (less than two to three weeks), inflammatory bowel disease and vascular graft infections and in patients postoperatively; it also appears efficacious in patients with acute osteomyelitis. A complementary rather than a primary role is suggested in renal, central nervous system, pulmonary and orthopedic diseases. Radioactive gallium is still recommended for chronic processes and computed tomography and ultrasonography in patients with localizing signs.

Pitfalls of the study include a reduced sensitivity in the first four to six hours after reinjection of labeled cells, demonstrated uptake in noninfected foci—such as recent hematomas, rarely in metastases and diffuse "inflammation"—investigational new drug status and the technical expertise necessary to label the leukocytes.

Alternative agents do not yet appear to offer significant advantages over oxine ^{111}In, although recent work has been reported with tropolonate ^{111}In and chloride ^{111}In. Prospects do appear encouraging for the development of an agent that will solve some of the major problems of labeled leukocytes—that is, kit preparation for rapid patient labeling, a drug that is noninvestigational and reliable results in hours rather than the next day. Studies are also in progress to assess the use of single-photon emission computed tomography to enhance diagnostic accuracy.

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Evaluation of Gastric Emptying Rates

Abnormal rates of gastric emptying, whether due to structural or to functional abnormalities, are particularly well suited for evaluation by nuclear medicine. It is often desirable to document, and if possible, quantify such abnormalities objectively because clinical complaints such as fullness may be hard to assess.

Gastric emptying mechanisms and rates differ for liquids and solids. Further, rates of liquid and solid emptying are related to the nature and amounts of materials consumed. Various tests have been used over the years to assess gastric emptying rates. For liquids, the saline load test is often used, which requires a nasogastric tube. Barium x-ray studies can be done using liquid either alone or in combination with "barium hamburger" patties; these require serial abdominal radiographic films (normally for six hours after the solid barium hamburger consumption).

More palatable, comfortable and physiologic studies using natural foods can be done with nuclear studies. The key to the nuclear medicine techniques is to affix a radiotracer to either a liquid or a solid material for assessing and accurately quantitating rates of emptying. The radiotracers are used in minute quantities and never affect the taste of the food. The solid phase of the study is usually applied by tagging scrambled egg for consumption as an omelet sandwich. For the liquid phase, 300 ml of a tagged liquid, such as orange juice, is used. The radiolabels have been found to be stable in vitro and in vivo. Liquid and solid meal studies can be done simultaneously by using two different radioisotopes. After the patient consumes the meal, sequential acquisitions are made with a gamma camera and stored in a computer. Regions of interest are then drawn around the stomach only. Counts from this area are obtained for each sequential accumulation and a graph of the counts versus time is drawn and can be extrapolated. The decreasing counts with time represent the rate of gastric emptying. The liquid study alone takes about 20 minutes of acquisition, while the solid or combined study is usually extended out to 90 minutes.

The normal time to empty half of each tagged material consumed (T½) is about 10 minutes for the liquid phase and 60 to 90 minutes for the omelet sandwich. An accelerated T½ reflects an abnormality such as a dumping syndrome. Conversely, a prolonged T½ reflects one of the several disorders associated with abnormal gastric retention.

Repeat studies are often helpful in evaluating the efficacy of therapy, such as a surgical procedure or the use of metoclopramide hydrochloride.

The nuclear studies described are physiologic and palatable. The amount of irradiation is less than in a barium hamburger meal and the study is more comfortable than a saline load test. A major advantage is the ability to provide more elaborate quantitative data; furthermore, unpalatability can, in itself, produce misleading results.

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Thyroid Cancer—Treatment Phase

Although most thyroid adenocarcinomas can be removed surgically, there is often uncertainty as to the completeness of the resection and the presence of local or distant metastases. For more than 35 years, radioiodine (iodine 131) has been used as adjunctive therapy in tumors that are of the differentiated cell type—papillary and follicular adenocarcinomas. It is the objective of radioiodine treatment to destroy all thyroid cancer tissue. The ability of residual or metastatic thyroid cancer to concentrate radioiodine is directly related to the serum thyroid stimulating hormone (TSH) concentration. Optimally, serum TSH levels should exceed 40 μU per ml. In the rare instances when TSH levels do not rise, exogenous bovine TSH may need to be given. Once adequate tumor uptake has been assured by radioiodine imaging studies, most nuclear medicine therapists recommend administering a fixed amount of radioiodine that varies from 100 to 200 mCi, depending on the extent of tumor distribution.

Following total thyroid cancer ablation, radioiodine imaging is ordinarily done at yearly intervals for three years and biennially thereafter for a minimum of ten years. If there is tumor recurrence, the patient is re-treated.

Whole-body imaging with radioiodine has been con-

Before prescribing, see complete prescribing information in SK&F CO. literature or *PDR*. The following is a brief summary.

WARNING

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: **Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired.** If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake. **Associated widened QRS complex or arrhythmia requires prompt additional therapy.** Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of triamterene and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (ACE) inhibitors can elevate serum potassium; use with caution with 'Dyazide'. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function. Thiazides may add to or potentiate the action of other antihypertensive drugs. Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

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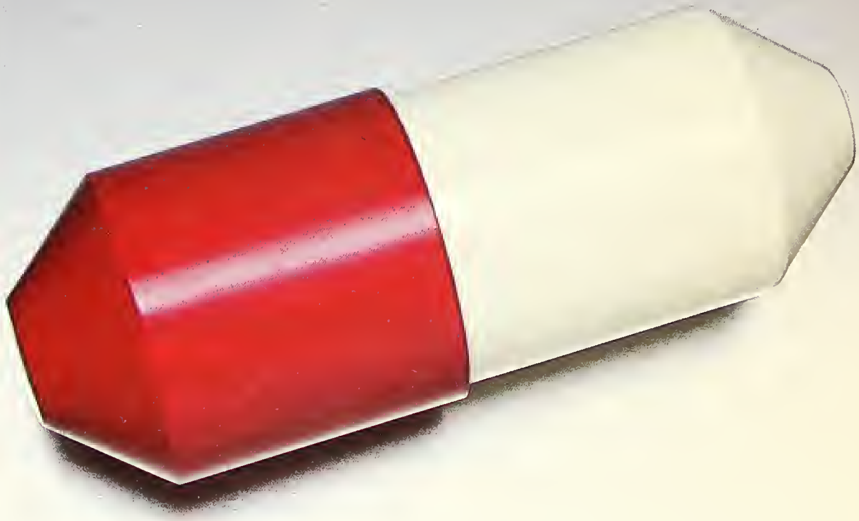

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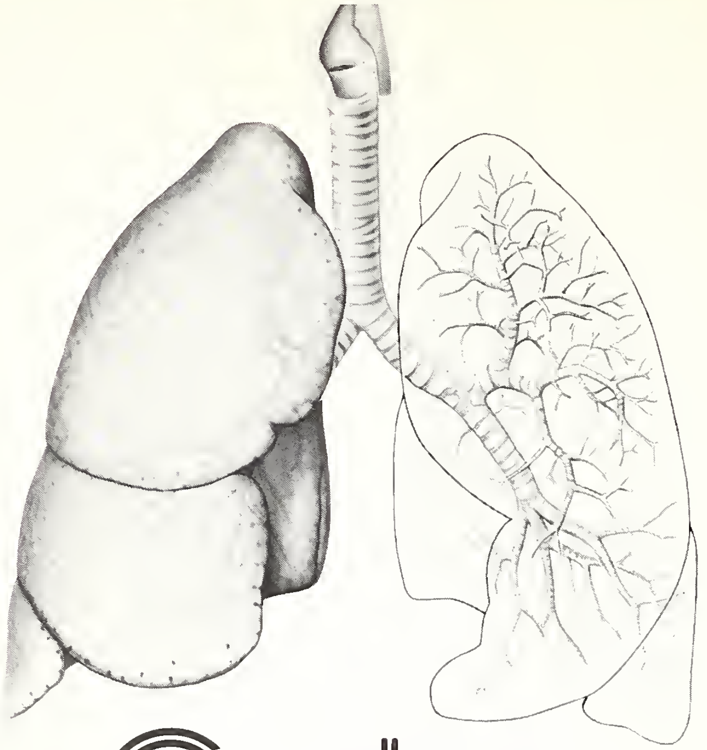

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Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:

- Discontinue Ceclor in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of nonsusceptible organisms.
- Positive direct Coombs' tests have been reported during treatment with cephalosporins.
- In renal impairment, safe dosage of Ceclor may be lower than that usually recommended. Ceclor should be administered with caution in such patients.
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon. Those reported include:

- Gastrointestinal (mostly diarrhea): 2.5%.
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, erythema multiforme, serum-sickness-like reactions): 1.5%; usually subside within a few days after cessation of therapy. These reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.
- Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1%.

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sidered the most sensitive means of detecting recurrent disease. It is a formidable procedure, however, requiring withdrawal of thyroid hormone replacement therapy and periods of symptomatic hypothyroidism. Recent reports suggest that the determination of the serum thyroglobulin level may be as sensitive in detecting recurrent thyroid cancer as radioiodine imaging and may supplement or even replace it. Because most thyroid adenocarcinomas secrete thyroglobulin, a significantly elevated level in a patient receiving thyroid hormone replacement is a clear indication for radioiodine imaging. Low levels appear to exclude the presence of recurrent thyroid carcinoma. Patients who have borderline elevations of serum thyroglobulin should be restudied with radioiodine after withdrawal of thyroid hormone. At the present time, the measurement of thyroglobulin levels is best considered complementary to radioiodine imaging in the management of thyroid cancer patients.

Despite 35 years of experience, the therapeutic efficacy of radioiodine in the management of thyroid adenocarcinoma remains controversial. A number of reports have appeared in recent years, however, that indicate increased survival and decreased tumor recurrence in patients who have received radioiodine therapy. The most favorable results have been obtained in patients with cervical or mediastinal lymph node involvement and thyroid bed residuals. Results have been less rewarding in patients with surgically unresectable tumor and gross residual disease and in patients with skeletal involvement. Accordingly, in some patients, limited or no therapeutic benefit is obtained with radioiodine therapy, whereas in others, large disseminated tumor masses disappear and no evidence of recurrence of tumor tissue can be shown after 20 years of follow-up. In view of this variability in response, it is important that radioiodine therapy be used judiciously in the appropriate clinical situation and for the histologic type of tumor that can be expected to be clinically responsive.

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Radionuclide Diagnosis of Varicocele in Infertility

Infertility has been reported to occur in as many as 15% of the normal population, and male infertility has been cited as the major cause in 30% to 50% of childless marriages.

Within this group of subfertile men, a scrotal varicocele has been identified as a well-established cause of decreased testicular function. It is also the most common surgically correctable cause of subfertility in men. While present in about 15% of the normal male population, the incidence is much higher (30% to 40%) in subfertile men, and surgical correction is associated with improvement in fertility in a large number of such patients.

Anatomically, a varicocele is caused by unimpeded retrograde venous flow in the internal spermatic vein, with subsequent dilatation of the pampiniform plexus. It is frequently associated with incompetence of the venous valves of the spermatic vein. It occurs on the left side in about 85% of cases and is occasionally bilateral, but rarely right-sided only.

The specific cause of abnormal testicular function in association with a varicocele is not established. It is most often felt to reflect a disturbance in the temperature regulation and an increase in scrotal temperature, but it may be due to retrograde flow of adrenal metabolites and renal hormones through the renal vein into the spermatic vein, affecting spermatogenesis. Collateral circulation connecting the venous system of the right and left testes would account for a bilateral effect from a unilateral abnormality.

A varicocele is frequently diagnosed by manual examination alone, based on palpability of the dilated pampiniform plexus (frequently during a Valsalva's maneuver), possibly in association with a decrease in the size of the ipsilateral testis. Physical examination, however, is not specific or highly sensitive. Semen analysis may show nonspecific abnormalities, including a "stress pattern," with abnormal sperm forms and decreased motility. The Doppler stethoscope and ultrasonography may assist in making the diagnosis but are likewise nonspecific. Venography is frequently diagnostic, but is invasive and often difficult to do.

The radionuclide demonstration of a varix is accomplished by labeling a patient's erythrocytes with technetium Tc 99m pertechnetate, the same agent used in routine cardiac imaging (gated cineangiography). The patient's cells are labeled by an in vivo technique with two peripheral venous injections. A radionuclide perfusion study is done at the time of injection of the isotope to evaluate for evidence of certain disorders, particularly for hyperemia, which would indicate an inflammatory condition.

The scrotal "blood pool" is statically imaged within minutes after injection, with the imaging done anteriorly and with the use of median raphe markers and upright (standing) and Valsalva's maneuvers as provocative measures.

Because the testicles are relatively hypovascular organs, the diagnosis of a varicocele depends on showing increased blood pool activity surrounding the left testis relative to the right. Additionally, regions of interest are developed by computer over each hemiscrotum to quantitate scrotal vascularity. A difference (left versus right) of greater than 10% to 15% is considered significant. Quantitative analysis may be impractical in the approximately 15% of bilateral varices, however, and visual analysis occasionally difficult if symmetry is present.

In clinical experience, the radionuclide examination has better sensitivity when compared with clinical suspicion alone. It may also confirm suspected but unproved varix formation or the presence of bilateral varices. The test represents an improvement in the detection and diagnosis of varicocele formation and offers a noninvasive, risk-free and cost-effective approach to diagnosis in subfertile men.

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Preoperative Scintigraphic Location of Parathyroid Tumors

Parathyroid scintigraphy has recently been reevaluated after the appearance of reports from Italy on the use of technetium 99m and thallium 201 for locating parathyroid adenomas. Hyperparathyroidism is a common clinical problem and operative localization of such tumors is sometimes difficult, with 5% to 10% of operations failing to localize a parathyroid tumor. It would be desirable then to identify their location preoperatively if a simple, noninvasive technique were available.

The technique initially reported was modified such that 2 to 3 mCi of thallium 201 is first administered, followed by 5 to 10 mCi of technetium Tc 99m pertechnetate. The patient is imaged over the thyroid-parathyroid region and the data computer acquired. Color images are generated using a special computer-comparison technique. Both analog and computer-processed color images can be used for localization.

As previously reported, single parathyroid adenomas were successfully localized preoperatively in 88% of patients without a previous parathyroid operation and in 86% of those with adenomas not located at a previous surgical procedure. In all, 83% of glands with secondary hyperplasia, 66% with primary hyperplasia and one patient with carcinoma were detected. Both published analog methods and color-comparison dual-isotope scintigraphy exceed the reported sensitivities of either ultrasonography or computed tomography. Using the color-comparison method, 87% of ectopic parathyroid tumors are successfully localized and patients with forearm transplants can also be evaluated. Modest goiters do not interfere and normal or suppressed parathyroid glands are not seen.

The benefits of dual-isotope localization techniques include the following: aid in differentiating preoperatively between hyperplasia and adenoma, shortened surgical time (and dissection), which ultimately lowers operative costs, and ability to evaluate cases in which a previous operation has failed to locate the parathyroid abnormality. Published studies strongly support the use of preoperative localization of parathyroid tumors by nuclear scintigraphy.

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Ureteral Reflux and Residual Volumes—Minimizing Irradiation

Vesicoureteral reflux in childhood has been clearly implicated as a cause of significant injury to the kidney. Reflux nephropathy is a complex issue and concerns both renal infection and direct renal injury caused by penetration of urine into the renal pyramid. Traditionally, children presenting with a urinary tract infection have been evaluated by intravenous urography and contrast cystography. Present methods of evaluation in many centers consist of an ultrasonogram of the kidneys with a radionuclide cystogram in female patients but a conventional contrast cystourethrogram in male patients. In either sex, cystography is done at about seven to ten days following antibiotic therapy, as it is likely that during the acute phase of an infectious process there may be sufficient bladder wall edema to prevent detection of clinically significant reflux.

Regardless of the method of initial evaluation, the radionuclide cystogram is the method of choice for sequential evaluation. The technique has been well described and it is simple to do. A small feeding catheter is aseptically inserted into the urinary bladder via the urethra. About 100 ml of sterile 0.1 normal saline is instilled into the bladder. A 250-μCi dose of technetium Tc 99m sulfur colloid is administered via intravenous tubing. The patient's bladder is then slowly filled to the point of spontaneous voiding. Continuous posterior renal scintiphotos and computer data that include the dome of the urinary bladder are obtained sequentially. A technique for indirect radionuclide cystography has been described; although it may be more physiologic, most observers feel that there is a substantial risk of missing clinically significant reflux using this method.

Following voiding, the residual urinary tract volume may be calculated. This is a simple measurement based on prevoiding and postvoiding urinary tract counts and the volume of urine voided. The amount of residual bladder volume has much less consequence than that retained in the entire collecting system, which should be determined when one calculates these values.

Although difficult to document, many observers feel that the radionuclide cystogram is more sensitive for detecting clinically significant reflux than the conventional contrast cystogram. This relates to the continuous monitoring and the greater ease of detection of small amounts of complete (to the level of the renal pelvis) reflux. The single most consequential aspect of the difference between radiographic contrast and radionuclide cystography is the radiation dose. A typical 30-minute radionuclide cystogram delivers about 30 mrads to the bladder wall, less than 5 mrads to the male gonads and about 2 to 3 mrads to the ovaries. These figures represent about 1/100th of the radiation-delivered dose from a well-done radiographic contrast cystogram.

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Bone Scintigraphy—No Diagnostic Equal

Despite major advances in computed tomography and nuclear magnetic resonance, bone scintigraphy remains the most sensitive and the most practical whole-body screening procedure for skeletal involvement with malignancy. For proper cost-effectiveness, however, bone scanning should be used routinely only to evaluate those malignant disorders with a substantial likelihood of skeletal dissemination. With the probability of bone scan positivity at diagnosis indicated in parentheses, these tumors include stages III and IV rhabdomyosarcoma (56%), neuroblastoma (51%), prostatic carcinoma (31.8%), Hodgkin's disease (27%), stage III breast carcinoma (22.5%) and all other lymphomas (14%). Cancers not warranting routine bone scintigraphy at diagnosis include bladder carcinoma (5% to 15%), cervical carcinoma (0% to 10%), asymptomatic bronchogenic carcinoma (6% to 8%), ovarian carcinoma (0% to 8%), uterine carcinoma (0% to 4%), head and neck cancer (1%) and stages I and II malignant melanoma (0% to 1%). In stages I and II breast carcinoma (2% to 6%), annual bone scans are appropriate to follow the disease because of the high probability of skeletal involvement at recurrence (7% to 58%).

Although 37% of bone scans are positive at diagnosis in patients with multiple myeloma, skeletal radiography is clearly superior in sensitivity. In all patients with malignancy, bone scintigraphy is appropriate to evaluate musculoskeletal pain or an elevated serum alkaline phosphatase level. In primary bone cancer, the bone scan can effectively show the extent of the primary lesion, spread to distal skeletal sites (11% to 45%) and calcified soft tissue metastases.

Among benign skeletal processes, the bone scan is useful to evaluate symptomatic osteoid osteoma (including surgical location), fibrous dysplasia, brown tumors and aneurysmal bone cysts. Its high sensitivity for acute osteomyelitis in adults (90% to 95%) can be equaled in children by the use of the three-phase bone scan. Combined with gallium 67 or indium 111-granulocyte scintigraphy, it is effective in assessing chronic osteomyelitis and in differentiating loosening from infection in joint prostheses. Subradiographic fractures, especially stress fractures, are best identified by bone scintigraphy. Paget's disease produces intensely positive labeling on a bone scan, so that bone scintigraphy is useful in evaluating the extent of pagetic skeletal involvement, including monostotic versus polyostotic Paget's disease and, to a lesser extent, in monitoring response to therapy or progression of disease. Temporomandibular joint disease is detected with 94% sensitivity by single photon emission computed tomography. The evolution of avascular necrosis (and other types of bone infarction) is well delineated by serial bone scans. Although the bone scan is abnormal in a large variety of arthritic and degenerative joint conditions, making positive findings highly nonspecific, it can be useful in establishing the presence of early inflammatory joint involvement before radiographic changes, in documenting the number of joints involved in the arthritic process and in ruling out arthritis by showing a normal bone scan. Detectable soft tissue lesions include tissue infarction (myocardial, bowel, rhabdomyolysis), some primary (neuroblastoma, breast, kidney) and secondary (osteogenic sarcoma in lung, carcinoid in liver) tumors and renal or urinary tract pathology (tumors, cysts, obstruction).

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Single-Photon Emission Computed Tomography Bone Imaging—A New Dimension in the Investigation of Back Pain

Low back pain is ubiquitous. It is the cause of much suffering and often causes great frustration not only to patients, but to physicians managing such patients. Radiography, including computed tomography (CT), may show no abnormalities or may show structural abnormalities that, in a significant proportion of cases, are resistant to even radical forms of treatment.

Nuclear bone imaging basically shows areas of increased bone metabolism. Conventional planar bone imaging often provides suboptimal information because of its inability to precisely locate abnormal areas in the spine, such as the neural arch, apophyseal joints or adjacent vertebral bodies. Single-photon emission CT (SPECT) is a new, increasingly available technique that adds relatively little cost to routine bone scanning. It has the ability to produce emission CT images ("slices") in multiple planes and thus to increase sensitivity, reduce ambiguities and accurately locate sites of abnormal activity.

Insofar as pain is likely to be directly related to areas of abnormal bone metabolism—that is, due to abnormal stress rather than simply the presence of structural abnormalities—these areas can be localized precisely with SPECT. Such areas of functional abnormality may or may not be associated with the presence or indeed the specific location of structural abnormalities. The etiology of the functional abnormalities and consequent abnormal areas on bone scanning may be associated with tumor, infection, fracture or abnormal local wear and tear. For instance, there is evidence that the presence of spondylolysis, possibly associated with spondylolisthesis, in itself does not always produce symptoms, and that a local area of increased activity on a SPECT scan in the region of a pedicle or facet is a more specific indicator of the origin of the back pain.

The potential to precisely locate the actual cause of back pain has widespread implications. The ability to discern an abnormality in a spine that is essentially normal on an x-ray film or CT scan has significant clinical advantages. Furthermore, the possibility of localizing precisely an area of abnormal bone metabolism associated with structural abnormalities should help decrease the failure rate of some major surgical procedures such as for spondylolisthesis if it can be shown beforehand that the site of abnormal bone activity is not in the region of the spondylolisthesis but rather is related to abnormal wear and tear in an apophyseal joint. This could be easily verified and treated by injection.

In general, the capability to differentiate and precisely locate functional, active disease from solely anatomic changes can aid in the more specific and effective management of patients suffering from back pain.

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Single-Photon Emission Computed Tomography Using Thallium 201 for Evaluating Coronary Artery Disease

Planar myocardial perfusion scintigraphy with thallium 201 is widely used for detecting, localizing and evaluating the extent of myocardial perfusion abnormalities and for differentiating infarcted from ischemic but viable myocardium in patients with possible or known coronary artery disease. With planar ^{201}T1 imaging, however, three-dimensional distribution of radioactivity in the myocardium is represented in a two-dimensional fashion, resulting in overlap of information among various myocardial regions. The planar imaging method, therefore, is not ideally suited to assessing location and overall size of ischemic and infarcted myocardium, the indices that are most predictive of prognosis in coronary artery disease. Single-photon emission computed tomography (SPECT) with ^{102}T1, using 180° or 360° rotational angular sampling, offers true tomographic studies of myocardial perfusion with reduced overlap of various myocardial regions and improved image contrast. With SPECT, the presence and extend of perfusion defects can be objectively quantified. Several experimental and clinical studies have now shown that ^{201}T1 SPECT can accurately measure the size of ischemic and infarcted myocardium. Thallium 201 SPECT can also accurately detect and locate myocardial perfusion defects in patients with coronary artery disease.

Interpretation of SPECT images requires knowledge of normal regional attenuation patterns and attention to possible artifacts caused by patient motion, breast tissue and inappropriate image reconstruction. SPECT is more difficult to do and interpret than planar ^{201}T1 imaging. Although SPECT is now well validated as an accurate myocardial imaging technique, the degree to which this method will replace the simpler, more widely used and less expensive planar ^{201}T1 approach remains uncertain.

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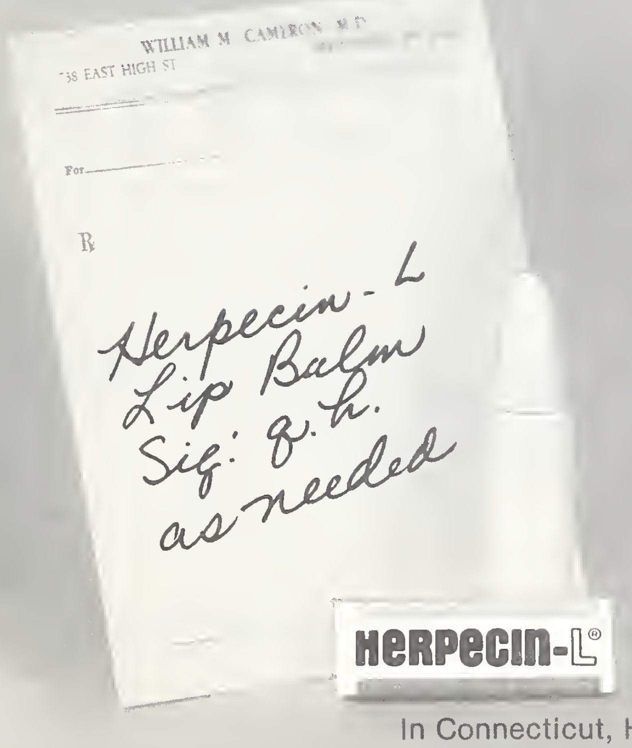

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Hospital Liability in Malpractice Cases For Negligence in the Granting and Renewal of Medical Staff Membership and Clinical Privileges

J. MICHAEL EISNER, ESQ.

During the course of recent inspections, the Connecticut Department of Health Services has criticized hospitals and medical staffs which do not specifically make provision in their medical staff bylaws for the continuing review of clinical privileges. The Department has focused on provisions for how additional privileges are to be granted, especially privileges for new procedures. It also has required that letters of reference solicited for applicants for medical staff membership request information with respect to the clinical privileges sought by the applicant.

These actions raise the question of whether hospitals and their medical staffs have a continuing duty to review medical staff membership and the delineation of clinical privileges so that imcompetent or unqualified physicians are not taken on, retained, or granted inappropriate clinical privileges.

A number of courts in other states have held that hospitals do have a continuing duty to review medical staff membership and the delineation of clinical privileges. If this duty is breached, then the hospital will be held liable for any negligence or malpractice in the hospital[1] by a physician whose credentials had not been properly reviewed. This duty has been referred to as the "doctrine of corporate responsibility," or the *Darling* doctrine.[2]

Although the "doctrine of corporate responsibility" has never been explicitly adopted by a Connecticut court, the Connecticut Court of Appeals nevertheless considered this type of claim in one case, but held without discussion that there had been no evidence of negligence in the granting of surgical privileges.[3]

However, since a large number of states have adopted the doctrine in credentialing cases, it is possible that it eventually will be adopted in Connecticut.

If the doctrine is adopted, "the pertinent inquiry" in a malpractice case, as to whether or not the hospital will be liable for the negligence of a member of its staff, would be "whether the hospital exercised reasonable care in the granting, renewal, and delineation of staff privileges."

As indicated, if found to have violated the rule, the hospital would be held independently responsible for the malpractice of the physician.

In a recent New York case,[5] an appellate level court held that where a plaintiff established that the defendant surgeon had been sued for malpractice four times in several years, the question of whether the hospital has failed "to develop and adhere to reasonable procedures for reviewing a physician's qualifications" was a question of fact to be decided by the jury.

In order to maximize the chances of avoiding liability under the doctrine, Connecticut hospitals and their medical staffs should substantially comply with the Medical Staff Standards set forth in the Joint Commission (JCAH) Accreditation Manual for Hospitals, and should carefully follow their own bylaws and rules and regulations[6] and the requirements of the Connecticut Public Health Code. If hospitals and their medical staffs follow this course, it is unlikely that they will be held to be independently responsible for the malpractice of one of their physicians.

In a case decided several years ago,[7] the Georgia court of appeals held that a hospital which had followed the JCAH credentialing standards had thereby acted in good faith and with due care and was not liable for the malpractice of a staff physician.

The Connecticut Public Health Code has little to say in regard to credentialing. A hospital is required to have a "[m]ethod of control of privileges granted to members of the medical staff" and a "procedure for recommending appointments to the medical staff."[8] As indicated, however, the Department has taken the position in the course of inspections that letters of reference should include comment on the privileges requested, and that the medical staff bylaws should address delineation of privileges issues, such as how privileges are granted for new procedures.

The JCAH Accreditation Manual (1986 edition) re-

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quires hospitals to establish a mechanism for the appointment and reappointment of members of the medical staff and for the granting and renewal of clinical privileges.[9] Required criteria for credentialing include evidence of licensure, training or experience, current competence, and health status. *Information obtained is to be verified.* With specific regard to reappointment, the Manual calls for a reappraisal including "information concerning the individual's current licensure, health status, professional performance, judgment, and clinical/technical skills, as indicated by the results of quality assurance activities and other reasonable indicators of continuing qualifications."

By way of summary and conclusion, the courts increasingly are holding that hospitals and their medical staffs have a duty to exercise care in appointing and reappointing physicians to the medical staff and in granting and renewing clinical privileges. The courts in a number of states have held that this duty is a continuing duty, and that if it is breached the hospital will be independently liable for the negligence or malpractice of the physician. Physicians who are involved in the credentialing process in Connecticut hospitals should substantially follow the recommendations of the JCAH Accreditation Manual, and should scrupulously follow their own Bylaws and Rules and Regulations.

Finally, the Connecticut Peer Review Act[10] appears to provide significant protection to physicians who participate in credentialing and quality assurance activities by providing that there shall be no monetary liability nor cause of action for damages against them with respect to matters arising out of peer review activities. In two cases arising under the Act, the courts have assumed that the Act applies to and thereby protects credentialing-type activities.[11]

REFERENCES

1. The doctrine of corporate responsibility is applicable to incidents occurring in the hospital, and ordinarily should not extend to the physician's office practice. See Pedroza v Bryant, 677 p 2d 166 Wash 1984.
2. Darling v Charleston Community Memorial Hospital, 211 NE 2d 326, is generally regarded as one of the seminal cases in the development of the doctrine of corporate responsiblity Ill 1965.
3. Bukley v Levallo, 2 Conn App 579, 1984.
4. Pedroza v Bryant, 677 P 2d 166 Wash 1984.
5. Raschel v Rish, 488 NYS 2d 923 App Div, 1985.
6. The Connecticut Supreme Court has indicated in another context that the failure to follow the hospital's rules and regulations is evidence of negligence. Van Steensburg v Lawrence & Memorial Hospitals, 194 Conn 500, 506, 1984.
7. Sheffield v Zilis, 170 Ga App 62, 316 SE 2d 493, 1984.
8. Connecticut Public Health Code (Regulations of the Department of Health Services) Sections 19-13-D3(c)(2)(A) (F).
9. See JCAH Accreditation Manual, Medical Staff, Sections 10.1, 10.4, and 10.5 Edition 1986.
10. Chapter 675a of the Connecticut General Statutes, Sections 38-19a et seq.
11. See Morse v Gerity, 520 F.Supp 470 (D Conn 1981); Commissioner of Health Services v William W Backus Hospital, 50 Conn Sup 188 (Super Ct Hartford-New Britian), 1984.

EPISODIC HYPERTENSION LINKED TO PANIC DISORDER

Persons who experience panic disorder, or panic attacks, marked by feelings of fear and symptoms such as shortness of breath, chest pain, palpitations, faintness or choking, may also be at risk for temporary elevations in blood pressure, according to a study in the June *Archives of Internal Medicine.* William B. White, MD, and Laurence H. Baker, PhD, of the University of Connecticut School of Medicine, Farmington, report cases of two men in their thirties who had episodes of high blood pressure associated with panic attacks. Both cases improved; one received therapy for stress reduction and the other (who also had high blood pressure at work) was treated successfully with a beta blocker. "Ambulatory blood pressure monitoring is useful in the diagnosis of this disorder and in assessment of treatment outcome," the researchers say.

An Overview of Two Hundred and Sixty Years of Pediatrics in New Haven: 1662-1921

HOWARD A. PEARSON, M.D.

The Quinnipiac (New Haven) Colony was founded by two Puritan dissidents, Theophilus Eaton a merchant and the Reverend John Davenport, who left England to escape economic and religious repression.[1] Their company left England in 1637. After wintering in Massachusetts where they found the religious climate to be unfavorable and all the good harbors already occupied, they sailed for the Connecticut coast having heard of the "rich and goodly meadows of Quinnipiac."[2] Eaton, Davenport and a company of about 500 settlers arrived on the banks of the Quinnipiac River on April 24, 1638 and established their colony. The company had no royal charter so they purchased the land which now makes up greater New Haven from the friendly Quinnipiac Indians. The purchase price was "twelve coats of English trucking cloath, twelve alcumy spoons, twelve hatchets, twelve hoes, two dozen knives," as well as the promise of protection from the still hostile Pequot Indians.[3] The pediatric history of New Haven began shortly thereafter.

Mr. Byron Rosseter, one of the earliest New Haven colony physicians, practiced in New Haven and Guilford in the 1650's and 1660's. He is notable for performing the first recorded autopsy in the American colonies on eight-year old Elizabeth Kelly of Hartford who had died during an epidemic in 1662.[4] The child's parents accused a neighbor, named Goody Ayers, of causing the child's death by witchcraft and appealed to the Connecticut General Court for redress. The court commissioned, and later paid Rosseter 20 pounds, to "open the Kelly's child." On the basis of his examination, he assigned the death to supernatural causes. What became of the accused witch is not known, for she and her husband left town immediately upon hearing of the General Court's action.[5]

One of the most towering figures in colonial Connecticut was not a physician. However, Governor John Winthrop, Jr. became renowned throughout early New England for his medical skills.[6] (Figure 1)

Figure 1
Portrait of Governor John Winthrop, Jr. (Courtesy of the Countway Library of Medicine)

Winthrop was born in Suffolk, England in 1606. He was educated at Trinity College in Dublin and studied law at the Inner Temple of London. He apparently soon became bored with the law and traveled extensively throughout Europe, where he conversed and studied with scholars and scientists, building the foundations for his subsequent medical activities.

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Presented at the History of Surgery Series, Yale University School of Medicine, February 8, 1982.

In 1631 he went to Boston following his eminent father, John Winthrop, Sr., who had founded the Massachusetts Bay Colony in 1630. After a short stint as his father's assistant, he again began to travel and between 1632 and 1647 established settlements in Ipswich, Massachusetts at Saybrook, and finally New London, Connecticut. He moved to New Haven in 1651, and shortly thereafter, he was elected Governor of Connecticut.

Winthrop was a considerable scholar and amassed a library containing more than 1,000 volumes. He corresponded in Latin with European confreres and in 1663 became the first American to be elected to fellowship in the Royal Society of England.

Despite his lack of formal medical training, Winthrop was probably the outstanding medical figure in mid-seventeenth century America. Cotton Mather wrote of Winthrop:

> "Wherever he came, still the Diseased flocked about him as if the Healing Angel of Bethesda had appeared in the place."[7]

Winthrop's medical "practice" was unusual in that it was in large part carried on by correspondence through the mails. The scarcity of physicians and Winthrop's willingness to give advice and prescribe free of charge resulted in his being frequently consulted. He was particularly interested in the medical problems of infants and children.

Winthrop's extant papers consist mostly of letters addressed to him from all over New England. Some of these are preserved at the Countway Medical Library in Boston where they have been studied by a number of medical historians including Oliver Wendell Holmes.

The Winthrop letters give insight into the medical problems of the mid-seventeenth century. Some of these are of particular New Haven pediatric interest because they concern children of prominent New Haven families.

Theophilus Eaton, a founder and the first Governor of the New Haven Colony, sought Winthrop's advice several times. Eaton complained to Winthrop that his second wife:

> "pinched (her stepdaughter) Mary until she was black and blue and knocked her head against the dresser which made her nose bleed much."

Three hundred years later, Dr. Henry Kempe, who trained in pediatrics at Grace-New Haven Hospital in the 1940's, gained international fame for his description of the "battered child syndrome," of which Eaton's daughter, Mary, was certainly an early example.[8]

William Leete, a Governor of the New Haven Colony and later a Governor of Connecticut, consulted Winthrop frequently about his many children. Perrigrine, his youngest child, had a severe chronic rash which started in the newborn period and caused "swelling and redness around the eyes." Later Perrigrine had "strangling fits, like convulsions." Leete also sought medicine to treat his daughter Graciana, who was described as being "puny and weak," perhaps an early example of the syndrome of failure to thrive. Leete also asked Winthrop's advice about his son Andrew's "starting fits."

Winthrop's written responses to these letters have not been preserved, but many of his prescriptions were saved. It is known that he used a sovereign remedy called "rubila" for many conditions. Rubila was considered to be most effective when given early and Winthrop exhorted; "Remember that rubila must be taken at the beginning of any illness." The formulation of rubila was kept a secret for three generations of physicians in the Winthrop family. Oliver Wendell Holmes' curiosity about Winthrop's panacea drove him to seek its composition.[9] Holmes wrote:

> "I had almost given up in despair when I found what appeared to be a key to the mystery. In the vast multitude of prescriptions contained in the Winthrop manuscripts, most of them written in symbols, I find one which I can interpret. Four grains of antimony with twenty grains of nitre with a little salt of tin, making rubila.
>
> Perhaps something was added to redden the powder, as Winthrop constantly speaks of rubifying or veridating his prescription, a common practice when powders looked too much like plain salt or sugar."

One of the major problems with rubila as a pediatric remedy was its very bitter taste. Governor Leete was administering rubila to his daughter, Graciana, for her failure to thrive. He wrote to Winthrop asking for directions:

> "to make her willing and apt to take it for she has grown marvelous awkward and adverse from taking it in beer. I entreat you to prescribe to us the ways in which it may be given effectually, else it may do much less good given by force."

Little is recorded about pediatric problems in New Haven for about 75 years after Winthrop's era. At this time, great epidemics of infectious diseases raged through Connecticut. These epidemics were studied and described in detail by Dr. Ernest Caulfield.[10] Caulfield was a member of the first housestaff of the Department of Pediatrics of the Yale Medical School in 1921 and a lecturer in the Department of Pediatrics for many years thereafter. Caulfield, who practiced in Hartford, devoted an enormous effort to the study of the early history of pediatrics in Connecticut. He pursued his research in the written records of Connecticut towns, in village libraries and in colonial cemeteries.

Caulfield described the New England diphtheria epidemic during the years 1735-1740 as the "most frightful epidemic of any childhood disease in American history."[11] One of the most appalling aspects of this epidemic was the frequent occurrence of multiple deaths in the same family. Caulfield told of multiple siblings dying of diphtheria within a week or two of each other. The Connecticut epidemic began in Stamford in 1735 with the deaths of five children in the family of Joseph and Mary

Smith. The epidemic reached New Haven in 1736. Seventy years later in 1811, Timothy Dwight wrote a statistical account of New Haven in which he said: "about the year 1736, the angina maligna was prevalent and extensively fatal." [12] In the summers of 1736-1737 in East Haven, then a parish of New Haven with a population of about 200, there were 40 deaths in children under 20 years of age. In 1736, 48 children died in East Guilford.

It was the nature of these clerical years to attribute epidemics to devine retribution, although it is unclear what sins could possibly evoke such a terrible response. In a sermon entitled, "The young people warned; the voice of God to the young people in the late terrible judgement of the throat distemper," preached five years later, the Reverend Jonathan Todd of Christ Church in Guilford wrote:

> "He must be a stranger in these parts of the world who has not heard of the desolation made by the throat distemper. Nearly five years ago we in this parish were visited with the same, and sundry very pleasant and hopeful young persons were taken away." [13]

The Connecticut epidemic spread north and east and finally ended in Killingsly and Pomfret in 1741. Caulfield estimated that the epidemic ultimately caused 37 deaths per 1,000 of the total population in Connecticut. Ninety-two percent of these deaths occurred in children.

The next great epidemic described by Caulfield was of bacillary dysentery, the so-called "bloody flux." As towns became larger toward the middle of the 18th century, this disease became increasingly prevalent. Bloody flux, which included typhoid fever, was recognized by its clinical and epidemiological characteristics including fever, bloody stools, short duration, occurrence during the summer, communicability, and high fatality rate.

A serious epidemic in New Haven and East Haven began in the year of 1742 and returned the following summer. In East Haven in 1742 and 1743 dysentery caused 73 deaths in a population of about 500. The deaths occurred disproportionally in children, and there were many instances of multiple deaths in the same family. Caulfield mentioned Daniel Potter of East Haven who lost four children and his wife to dysentery during the two weeks of September, 1743.

These were indeed perilous times for children. Caulfield wrote:

> "In addition to diphtheria, dysentery, measles, and scarlet fever—small pox, influenza and tuberculosis should certainly be included in the list of common diseases of colonial children. A suprisingly large proportion of them also had worms. Death frequently followed from eating poisonous berries, thornapple seeds, and so-called mushrooms. Hardly a year went by without a report of a child fatally burned. More were drowned from falling off wharves or into unguarded wells. And finally, in addition to all these hazards, an incalculable number suffered from other serious, non-contagious diseases, particularly convulsive fits. It seems a little surprising sometimes that any of them survived."

Mortality during infancy and childhood was in the range of 30%-40%. One of the most striking examples of this was the family of the renowned colonial preacher, Cotton Mather. He had fifteen children, and outlived fourteen of them! [14]

Medicine in America during the 17th and 18th centuries was not the sole domain of physicians, for clergymen and educators also took an interest. This activity is reflected in a communication by Thomas Clap, a straight-laced congregational minister, who was president of Yale from 1745-66. [15] Clap wrote to the editor of the Boston Gazette: [16]

> "A few days ago, a child belonging to Mr. Moses Belcher of this town had a cutaneous eruption resembling the Chicken Pox. Upon opening some of the pustules there appeared to be a great number of animals which were scarcely discernable by the naked eye, but seemed to be animals by their swift motion in crawling.
>
> One of them was brought to the College and being viewed under the microscope, it appeared to be a perfect turtle with upper and lower shells.
>
> I judge that it was about a thousand part so big as a louse."

In 1969 Dr. Thomas Cone of Harvard called Clap's letter, which probably described a case of scabies, to the attention of Kingman Brewster, who was then president of Yale University. Brewster responed to Cone:

> "Alas, we presidents are so dull these days! But I will never feel quite the same about an itch again." [17]

Descriptions of pediatrics in New Haven in the late 18th century are found in the *Cases and Observations; by the Medical Society of New Haven County* published in 1788. [18] This remarkable document was the work of members of the New Haven Medical Society which had been founded in 1784 by a group of 13 physicians for the purpose of improving themselves and exchanging medical knowledge. This volume is acknowledged as the first transactions published by a medical society in the United States. The transactions contain a total of 26 clinical reports contributed by ten different physicians. Ten reports, almost half of the total, concerned problems in children from the New Haven area.

Dr. John Spaulding, a prominant New Haven surgeon, described the successful treatment of a seven year old boy with a depressed, comminuted skull fracture.

Dr. Eneas Munson, a beloved New Haven physician, and later the first Professor of Materia Medica of the Yale Medical School, told of a 14 year old servant girl who developed "locked jaws" after a fall from a second story window. Two applications of electric shock from a "moderately charged receiver," (apparently a Leyden jar), provided a rapid and complete cure. It is likely that this was a case of hysteria because no other signs of tetanus were described.

Dr. Ebenezar Beardsley, a popular New Haven physician and apothecary, described pediatric problems in three reports. The first case was a five year old boy with signs and symptoms of severe dehydration and shock who died of enteritis. Beardsley performed an autopsy which showed inflammation of the intestines, and specifically, no worms were found. At that time many childhood problems were ascribed to worms. Beardsley quoted Allen, a contemporary writer, who advised the practitioner treating children:

> "if he meets any symptoms he cannot readily account for, place it to the account of worms."

Beardsley argued that the findings in his case argued against such an all-inclusive diagnostic approach.

He next described a five year old girl with internal hydrocephalus. She developed signs and symptoms of rapidly progressing increased intracranial pressure. Following her death an autopsy by Beardsley, which included opening the skull and sectioning of the brain, revealed marked dilation of the third and fourth ventricles.

Beardsley's final report was a case of fatal pneumonia in a seven month old girl for which he prescribed emetic tartar, pedilivum and diluting drinks. An autopsy revealed extensive inflammation of the lungs. Beardsley expressed great regret for not having bled the child, because he could find "no vein from where a proper quantity of blood could be obtained."

Dr. John Nesbitt, the next contributor, was a Scot trained in Edinborough. Nesbitt's report described a two year old girl with nausea, diarrhea and vomiting, violent fever, abdominal distension and great restlessness. Nesbitt ascribed these symptoms to dysentery and prescribed emetic tartar to "purge the acrid offending matter." Within three hours the child passed 32 large round worms, measuring eight to nine inches in length, "all alive and squirming." The child rapidly recovered from what was undoubtedly intestinal obstruction caused by ascariasis. Nesbitt's other report described the surgical repair of the accidentally severed Achilles tendon of a ten year old boy.

Dr. Benjamin Gale of Killingworth was the only practitioner outside of New Haven County who made a contribution to the transactions. His report took the form of a letter telling of the wanderings of a rabid dog through Killingworth and Guilford. During its travels the dog bit 15 other animals and two children. Dr. Gale treated both children with yellow sulfate of mercury. Neither developed rabies and Gale proposed that this salutory outcome was a result of his treatment.

The last two cases in the transactions merit particular note. Dr. Leverett Hubbard, who had been a Revolutionary War Militia commander, discussed attending a very difficult delivery which involved internal inversion of a stillborn infant "monstrosity" with a huge perineal tumor, probably a sacrococcygeal teratoma. The tumor had been the presenting part and had impeded delivery as well as causing considerable confusion to Dr. Hubbard during his pelvic examination! A wood engraving of this case is the only illustration in the transactions. (Figure 2)

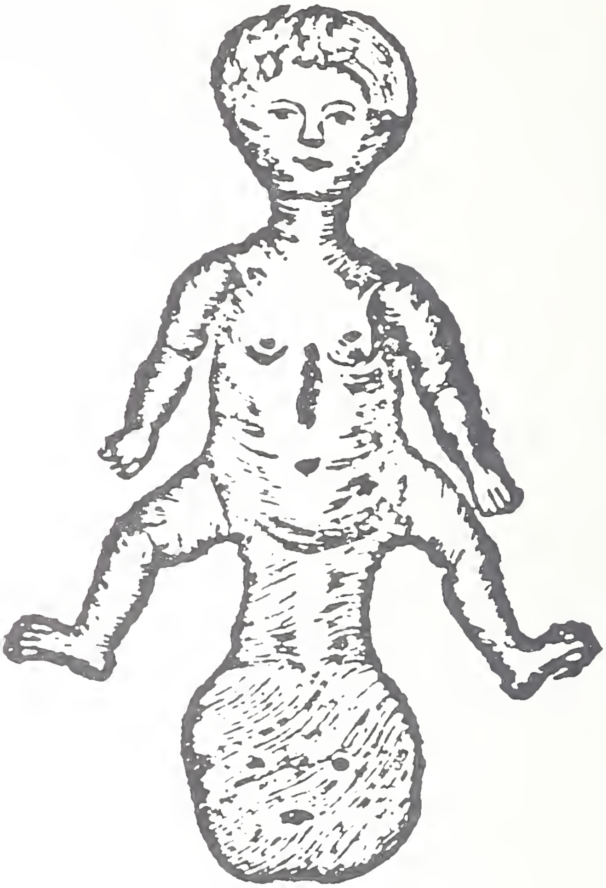

Figure 2
Leverett Hubbard's case of a fetal "monstrosity" with a large perineal tumor. Reproduced from Cases and Observations by the Medical Society of New Haven County, 1788.

The most renowned report was written by Dr. Hezekiah Beardsley. (Figure 3) He was one of three physician brothers. He moved from Southington to New Haven in 1782 where he lived until his death from tuberculosis in 1790. He practiced medicine with his brother Ebenezar and they shared an apothecary shop on Chapel Street between Church and Orange Streets. After his death, Beardsley was buried on the New Haven Green. Later his headstone was moved to the Grove Street Cemetery where it was rediscovered in 1930 by Dr. Walter R. Steiner. [19]

Beardsley's contribution was the description of a "schirrus" in the pylorus of an infant. He described a male child, son of a Southington farmer, who had the onset of "constant puking" in the first week of life. The child vomited milk and every other substance it received in its stomach. A number of physicians were consulted and a variety of medicines were used with little or no effect. Beardsley first examined the child when he was two years of age and noted him to be "lean with a pale countenance and

Figure 3
Portrait of Dr. Hezekiah Beardsley. (Courtesy of the Yale University Art Gallery)

wrinkled skin like that of old people." The child's condition changed very little until his sudden death at five years of age. Beardsley did not hear about the boy's death until two days later but he went to Southington immediately. He wrote:

> "This later period, the almost intolerable stench and the impatience of the people who had collected for the funeral prevented so thorough an examination of the body as might otherwise have been made. The stomach was unusually large; the coats were about the thickness of a hog's bladder. The pylorus was invested with a hard compact substance or schirrosity which completely obstructed the passage into the duodenum to admit with greatest difficulty the finest fluid.
>
> After a little more exploration, the necessity of interring the body that evening, put a stop to any further examination."

Beardsley's report was reprinted in entirety in the 1903 *Archives of Pediatrics* after its rediscovery by Sir William Osler. [20] Osler states that Beardsley had described the disease of hypertropic pyloric stenosis of infancy "clearly and accurately." Modern physicians might dispute this as a typical case of infantile hypertrophic pyloric stenosis which is usually not symptomatic in the first week of life, and if not fatal in infancy, usually regresses spontaneously. [21] Although subsequent research has uncovered earlier cases from England, Beardsley's report is notable for its clinical and pathological descriptions and for its uniquely American origin. In his honor the Connecticut Chapter of the American Academy of Pediatrics is named the Hezikiah Beardsley Society.

The diseases of infancy and childhood were taught at the Medical Institution of Yale College shortly after it was opened in 1813, well in advance of other American medical schools. Dr. Eli Ives, one of four generations of New Haven physicians, lectured to an estimated 1,500 Yale medical students on the Diseases of Children for nearly 40 years between 1813 and 1852. (Figure 4) Some of his pediatric lectures, meticulously recorded in flowing penmanship by Yale medical students during this time, are preserved in the manuscript and archives section of Yale University's Sterling Library. [22] The Ives' Lectures on Diseases of Children are the first systematic and dedicated American course of instruction in what today is known as the specialty of pediatrics. During the 1820's, Ives' title at Yale was Professor of Materia Medica, Botany, and the Diseases of Children and so he held the earliest American academic appointment in pediatrics.

Figure 4
Portrait of Eli Ives, M.D. by Nathanial Jocelyn, circa 1827. (Courtesy of the Yale University Art Gallery)

There were other early 19th century academic physicians with demonstrated interest and involvement in children and their diseases. These pediatric pioneers included Benjamin Rush and William Potts Dewees of the University of Pennsylvania and John Eberle of the Jefferson and Cincinatti Medical Colleges. However, these early physicians had formal academic titles in other departments and they did not present separate substantive courses in pediatrics at their institutions.

By the latter half of the 19th century pediatrics began to attain academic recognition in the United States. Dr.

Abraham Jacobi of New York established a children's clinic at the New York Medical College in 1861. He held the academic title of Professor of Infantile Pathology and Therapeutics and lectured on the diseases of children. Jacobi is generally regarded as the "father of American pediatrics."[23] In Boston, it was not until 1893 that Dr. Thomas Morgan Rotch was appointed to a professorship in the Diseases of Children with a chair on the Harvard faculty.[24]

It is apparent that Eli Ives' appointment at Yale as Professor of Materia Medica, Botany and the Diseases of Children in 1820 and his formal courses in the Diseases of Children given between 1813 and 1852 considerably antedated those of other early leaders in American pediatrics. Eli Ives was America's first academic pediatrician and Yale has the honor of first recognizing the importance of teaching this discipline.

The manuscript and archives section of Yale's Sterling Library has seven different copies of students' notes of Ives' Lectures on Diseases of Children. Each is handwritten, on pages measuring about 6 by 8 in. carefully indexed and bound. In these lectures, recorded throughout a quarter century span from 1813 to 1840, each student's version differs somewhat from the others. However, it is striking how little the content changed, reflecting the static condition of medicine during this time. The lecture notes indicate that Ives was widely read in the national and international medical works of his day and communicated, not only with his local confreres, but also with physicians throughout the country.

The 1829-30 notes recorded by Dr. Alvan Talcott, Yale Medical School class of 1831, who practiced in Guilford for 40 years, are the most extensive of the available versions. They appear to be verbatim transcripts of the lectures and are written in the first person as Ives must have delivered them. The lectures encompass 43 topics from angina laryngea to worms. They were delivered over a three month period and must have represented a major component of the medical curriculum at Yale during this time.

The lectures of Eli Ives as recorded in his students' notebooks reflect the scientifically primitive state of American medicine during the early and middle 19th century. Like most physicians of his era, Ives ascribed almost all illness to offending substances in the primae viae (gastrointestinal tract) or to unbalanced humors in the blood that induced excessive tension or laxity in the nervous, vascular, or digestive systems. These peccant substances or actions had to be removed or transposed by bleeding, purging, puking, sweating, or blistering to restore the system to health. Ives was a polypharmacist and used an extraordinarily broad array of medicinals and drugs, often derived from the indigenous flora of New Haven. It was said that he "prescribed with a hoe from the resources of his wonderful botanical garden."[25] His therapeutic sheet anchors were calomel and ipecac.

Ives ascribed many diseases of infants and children to developmental or endemic phenomena. Problems in the first month of life were often attributed to retention of meconium. Dentition either caused or aggravated many diseases during the first 6 years of life and lancing of the gums were considered essential. Worms were nearly ubiquitous, and many childhood problems were ascribed to them. The germ theory was not widely accepted until after Ives' death, and the lectures reflect his difficulty in accepting "contagion" in the genesis of disease. Rather, he believed unfavorable atmospheric conditions or bad housing and diet were more likely causes.

In explanation of why he selected the diseases of children for presentation, Ives recalled that during his medical training, he had received no instruction on this subject. Yet, as a new physician in practice, he had often been asked to attend sick infants and children and he encountered diseases that were not described in any book. Established physicians apparently avoided young children as patients, perhaps because of the high mortality of many pediatric diseases and because children could not communicate verbally. Ives noted that the care of infants and children had, by default, been relegated to nurses and midwives. He deplored entrusting the care of children to a "class of society the lowest in point of intellect." His lectures to Yale medical students were designed to address this problem. His lectures reveal Ives to have been an astute diagnostician who had an enormous clinical experience which he applied to his practice and teaching. Good sense, humility, wit, and affection for children are evident.

Following Ives' retirement, teaching of Pediatrics continued but at a markedly reduced level as part of the Obstetrics course. Records concerning the care of children and their diseases during the fifty years after Ives' death are scanty, but two municipal institutions were established which had an important influence on Pediatrics in New Haven. In 1870 the New Haven Health Department was founded. Its missions were the gathering of vital statistics about the city's populace and conducting public health measures. In 1872 the New Haven Dispensary was established for the care of the poor of New Haven and it became affiliated with the New Haven Hospital and the Medical School. For 40 years the pediatric ambulatory activities of the New Haven Hospital and the teaching of pediatrics of the Medical School were centered in the Dispensary, located in the Hope building on the corner of Cedar Street and Congress Avenue. These services were assumed by the clinics of Grace-New Haven Hospital in the 1940's.

The 50 years between 1875 and 1925 were marked by major advances in child welfare. These were highlighted in a Health Survey of New Haven published in 1926 by C.E.A. Wilson, a Yale Professor of Public Health.[26] In 1877 New Haven's population was about 50,000. The infant mortality during the first year of life was 200 per thousand births. The diagnostic categories which predominantly accounted for this high mortality were infectious processes, especially respiratory diesase, diarrhea and other diseases of early infancy. By 1925, the death rate had fallen to 65/1,000 births. Much of this improvement did not reflect advances in medical science because effective, specific therapy for many diseases was still a half a century or more away. Rather, it was primarily a result of social and public health measures.

The Visiting Nurses Association (VNA) was founded in 1904 to serve the poor of New Haven. The organization grew rapidly from a single nurse, Miss Mary Grace Hills, to more than 60 nurses. The VNA became extensively involved in both prevention and education and by 1920 was conducting 25 well baby and preschool conferences each week. Clinics also were held to provide prenatal education in nutrition and hygeine.

Contemporaneous with the growth of the VNA was New Haven's progress in sanitation, especially the processing and handling of foods and milk. This was reflected in the decreasing mortality rate from diarrheal disease including so called "cholera infantum" or "summer complaint." Pasteurization, which ultimately ensured safe milk, was controversial into the twentieth century. It was believed that heating milk made it undigestable for babies and not until the turn of the century was it generally appreciated that pasteurization prevented transmission of human diseases. In 1908 Chicago became the first city in the world to enact compulsory pasteurization. Agencies to inspect milk and food were set up by the New Haven Health Department in 1905, and by 1922 pasteurization of all milk sold in New Haven had become mandatory. Combined with a safe municipal water supply and an expanded sewage system, summer became much safer for infants in New Haven.

Grover Powers, in a 1935 review of infant feeding, described the infant mortality in New Haven in five year intervals from 1870 to 1930.[27] He believed the marked decrease in the mortality rate which occurred during this time was related primarily to public health and social welfare measures rather than to physicians.

Comparable improvement was seen in other infectious diseases. Death rates from diphtheria in New Haven showed little decrease until 1895 when diphtheria antitoxin was introduced. The use of anti-toxin became nearly universal after 1896 and diphtheria as a killer of New Haven children assumed a low prevalence, further decreased by the introduction of the Schick Test and active immunization after 1920.

A separate pediatric service was not established at New Haven Hospital until 1920. In 1886 a report of the Lady Visitors deplored this state of affairs:

> "There is one subject, however, to which the Lady Visitors feel that they must most urgently call to the attention of the Prudential Committee and, if possible, that of the public. It is to that very great need of a separate Children's Ward. At present children and nervous women-patients are in the same ward to the great detriment of both.
>
> Patients with nervous complaints should not be subjected to the noise which is often torture to them. Nor should the poor children, whose little lives are dull enough, be deprived of the small amount of pleasure and fun that is possible for them."

At the turn of the century, the few hospital beds for children were in a small section of the Gifford Ward, which was razed in 1914. These beds were attended by the general medical staff.

Pediatrics at Yale Medical School at the turn of the century was a small subsection of Internal Medicine. The lectures on diseases of children were given by Dr. Louis B. Bishop who retired from medicine in 1908 to pursue his true love, Ornithology. Dr. H. Merriman Steele, who succeeded him as lecturer was probably the first New Haven physician to limit his practice to children. Steele came to New Haven in 1903 as an assistant or houseofficer in pediatrics and pathology. Upon Dr. Bishop's resignation, Steele was promptly appointed as Instructor. He assumed the task of teaching pediatrics to the medical students in their junior year as well as pursuing his own busy practice. At this time, the total curricular commitment to pediatrics was about 20 hours.

The inevitable conflict between teaching and practice by part time faculty is reflected in a curriculum critique prepared by the Yale Medical Student Council in 1910.

> "Dr. Steele, when able to meet his classes, succeeds in meeting all requirements in the presentation of his subject. Unfortunately, owing to the large percentage of 'cuts' received from him, it is felt that the broad training in children's diseases a student should have, is *not* received. We suggest that Dr. Steele analyze his reasons for 'cutting' and if possible arrange a more opportune time for his recitation hours."

Other early New Haven pediatricians included Dr. Joseph I. Linde who later became head of New Haven's Health Department. Drs. Donald W. Porter and Dr. William C. McGuire were Yale Medical School graduates who received pediatric training at New Haven Hospital in the 1910-1920 period and then entered private practice in New Haven.

1913 was a pivotal time for the Yale Medical School. In response to the Flexner Report, an agreement was negotiated between Yale University and New Haven Hospital which provided for full time university chiefs in Medicine, Surgery, Pathology, and Pediatrics. However, a professor of Obstetrics and Gynecology was substituted for Pediatrics and instruction in the diseases of children remained under Internal Medicine. In 1916 the Executive Committee of the Medical School again recommended recruiting a Professor of Pediatrics. However, the clinical and laboratory facilities to attract an outstanding individual were hopelessly inadequate and little progress was made.

By 1920, reconstruction and renovations provided the space for a "modern" 12 bed Children's Ward on 2 West.

This was in addition to 35 beds for children's infectious diseases in the Isolation Building which had been built in 1912 on the corner of Davenport and Howard Avenue. The Dispensary continued to provide ambulatory teaching material. Obstetrical and newborn inpatient facilities were located in the South Ward where 20 obstetrical beds and a nursery were present. Facilities and adequate pediatric teaching material were assured. The time was propitious to appoint Yale's first modern Professor of Pediatrics.

The man selected was Dr. Edwards A. Park. Park was a graduate of Columbia's College of Physicians and Surgeons. He was trained in biochemical research techniques at Columbia and in Germany, and then worked for nine years at Johns Hopkins in John R. Howland's biochemically oriented Department of Pediatrics. Park was a member of the Hopkins' research team whose investigations into the cause and cure of rickets culminated in the discovery of Vitamin D in 1923. Thus, when Park came to New Haven in 1921, he was already a highly regarded academician and investigator.

In an incredibly brief time Park, assembled an excellent faculty and recruited a promising housestaff. Yale's first Pediatric Departmental photograph is shown in Figure 5. In addition to Park, the faculty consisted of Grover F. Powers, who was to become the dominant figure of New Haven pediatrics for the next thirty years; Alfred T. Shohl who was an authority on body composition and mineral metabolism and was also the inventor of Shohl's solution; Ethel Dunham and Martha Eliot who later became national leaders in the United States Children's Bureau, Eliot as Director and Dunham as an expert in prematurity; Dr. Marion Putnam who became Director of the Roxbury Children's Center and Professor of Psychiatry at Harvard; and Dr. Ruth Guy who became head of Pediatrics at Peking Union Medical College in China. The residents included Frank Bobbot, who later became Chairman of Pediatrics and Dean at the Long Island Medical College; Ernest Caulfield, the Hartford pediatrician and medical historian mentioned earlier; and Dr. Joseph Weiner. Dr. Weiner, a New Haven "townie," was Yale's first All-American in basketball and went on to practice pediatrics and allergy in New Haven for 60 years.[28]

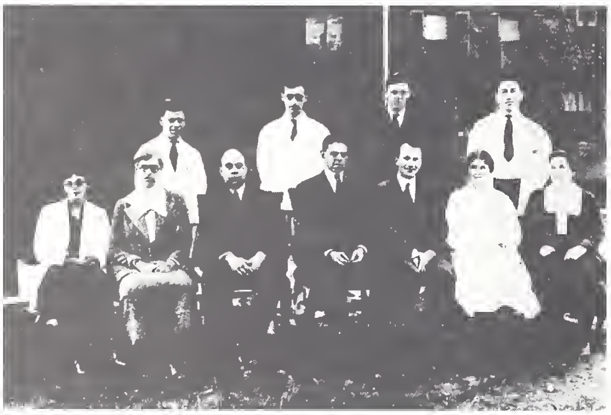

Figure 5

The Department of Pediatrics, Yale University School of Medicine, 1921-22. Standing left to right: Caulfield, Battley,* Bobbot, Weiner. Seated left to right: Guy, Dunham, Powers, Park, Shohl, Eliot, and Putnam.

*I have no information about these physicians.

Park remained at Yale for only five years, returning to Johns Hopkins following the death of John R. Howland. Grover Powers, who had briefly assumed a position at the Henry Ford Hospital in Detroit, returned to Yale as Professor and Chairman. Under the leadership of Powers, the next 30 years were the golden years of Pediatrics in New Haven.

I have chosen to conclude this overview of New Haven pediatrics with the establishment of the Yale Department in 1921. The modern era of New Haven pediatrics is the history of the Department of Pediatrics under five chairmen; the tremendous growth of fulltime faculty and community pediatric practitioners; the explosion of biomedical information and technology; the increased awareness of psychosocial issues in pediatrics; and the development of effective prevention and therapy for many of the traditional scourges of childhood.

In 1952, Ernest Caulfield wrote to T.E. Cone an opinion which I believe is relevant to the modern history of pediatrics in New Haven:

> "Some time someone will write the history of American Pediatrics; but not immediately, I hope, because it is much too soon to appraise properly the revolutionary changes of the past few decades."[29]

The history of the last sixty years of pediatrics in New Haven is rich and complicated, acted out by many interesting, dedicated and even controversial figures. I believe that this modern history cannot be assessed until some of the dust has settled!

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IN THE AFTERMATH OF THE CHERNOBYL NUCLEAR POWER PLANT DISASTER, the AMA has formed a new committee to address the health problems associated with nonmilitary radiation incidents, emergencies, and accidents. The Advisory Committee on Nonmilitary Radiation Emergencies will guide organizational activities at the state and local levels, as well as serving as a body of expertise at the national level.

Among observations developed at an initial meeting of the seven-member panel last month:

- Health and medical effects, rather than engineering and technical problems, are of primary concern to the public.
- Management of radiation emergencies involves treatment of physical and emotional damage to human beings.
- An almost complete absence of physician involvement in planning currently exists.
- Physicians have not been organized on a local, regional, national, or international basis to respond to the need for information on radiation effects on a voluntary basis, nor are physicians appropriately utilized by government agencies responding to the need for public information.

"Many physicians are knowledgeable about how to respond to radiation emergencies, and others have adequate training to help assess the health consequences of radiation incidents," said committee Secretary William R. Hendee, PhD, AMA vice president for science and technology. "The desired level of physician involvement would lead to a reasonable professional and public understanding of nonmilitary radiation incidents and emergencies."

The advisory committee recommended developing an action plan that would increase physician involvement at the community level, through state and county medical societies, and improve national recognition of physicians as expert resources for government agencies and the media. Among the suggestions:

- State and county medical societies should assist hospitals in developing emergency response plans.
- The AMA should provide information packets to state and county medical societies.
- State and county medical societies should advise the media, civic organizations, government agencies, and educational groups of the availability of experts to address health aspects of radiation incidents.
- The AMA should advise federal and state governments of the need for physician input.
- Medical societies should convene local groups of experts to develop planning and communications activities.

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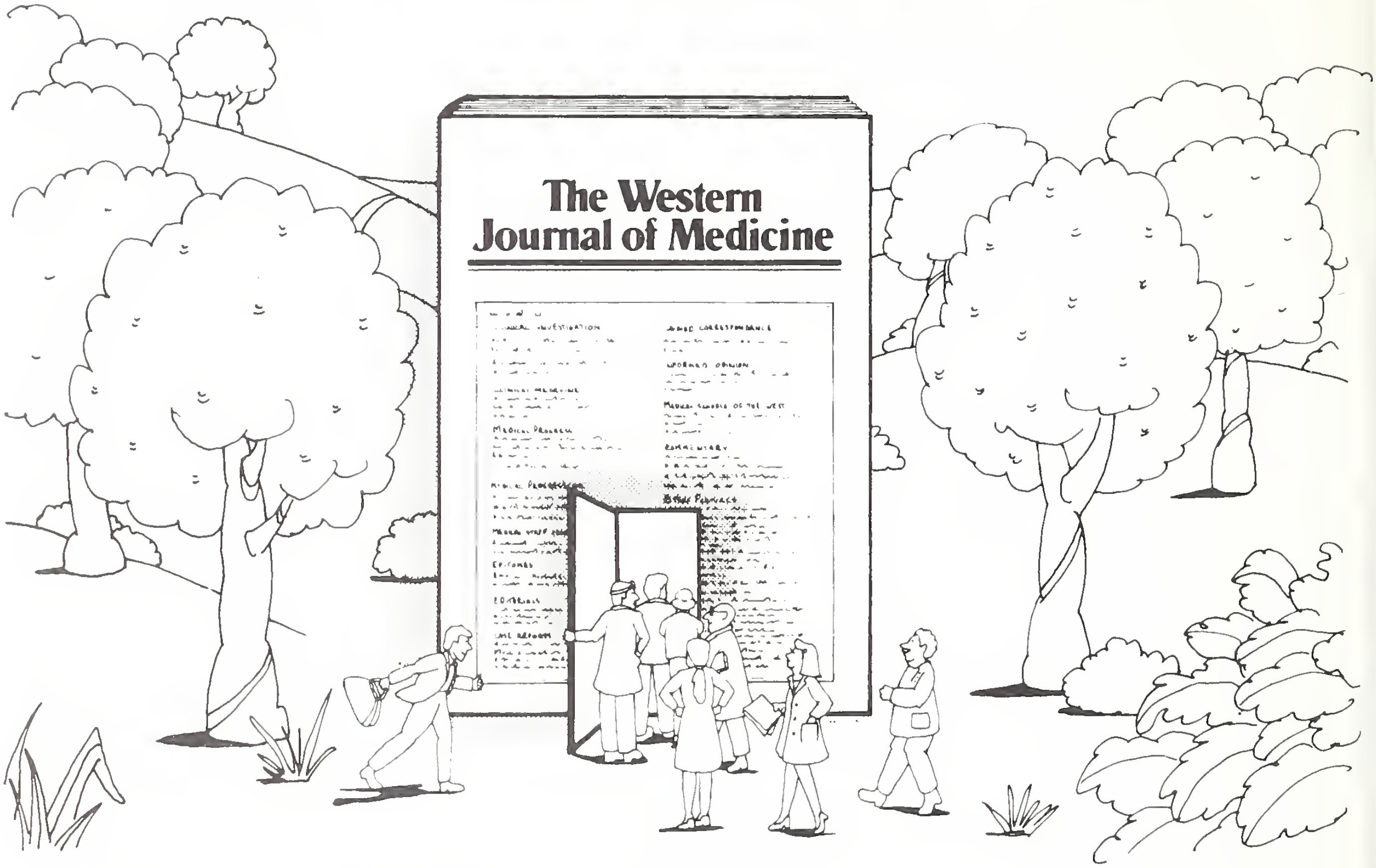
Inside Information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CPRO and Hereafter

EDWARD A. KAMENS, M.D.

When, in response to federal legislation mandating the establishment of Peer Review Organizations, the Connecticut State Medical Society voted to engage in the open competition for the contract to perform peer review in Connecticut, it tacitly acknowledged a somewhat unpleasant verity of present day medical life.

The unhappy circumstances of runaway health care costs, heightened patient expectation, lowered public esteem of the establishment and increased concern by business and industry regarding its share of the bill, formed a concatenation of irrepressible forces that begged for relief from a perceived staggering financial burden. The discourse always centered on the "runaway" costs engendered and on the rising share of the Gross National Product that was being "eaten up" by health care.

It was not surprising then that legislation initiated at that time focused on cost containment as the primary objective to be attained. Concomitantly, the awareness of some of the perverse incentives of the prospective payment system made it mandatory that peer review organization devote an ever increasing portion of their time on issues of quality of care. With increased congressional concern about quality of care issues came a barrage of pejorative allegations that made it difficult to separate fact from fiction or inadvertence from "Horrendoma."

Ever so slowly, data accumulated over a period of more than a year has begun to emerge in sufficient quantity to merit validity. Ever so slowly, impression and conjecture are giving way to facts.

The CPRO experience has been a harsh one for those physicians who have been placed in the position of acting as buffers between the physicians of this state and the often intransigent nature of federal regulation. Only commitment to the principle of self-discipline and peer review has kept the cadre of physician reviewers at a task so often tainted by personal animus. This feeling of animosity has been compounded by heightened resentment of what all physicians perceive as an attitudinal change towards the quality of care rendered to the elderly.

Yet, it is that very concern that mandates the continued support of those affected by the process.

The establishment of a peer review system run by physicians as opposed to a purely utilization review system run by non-physicians has permitted a modicum of physician influence on the system. Not only are the criteria by which review is conducted professionally developed, but ultimately all negative determinations are made only by physicians and are subject to appeal to a physician of the same specialty as the attending physician. Since it is true that decisions made must be within the bounds of what is mandated by regulation, it should come as no surprise that a physician organization is often in conflict with those charged with oversight of the peer review organization. Although obligated to perform within the constraints contractually imposed upon it, the peer review organization has succeeded in ameliorating restrictive conditions on numerous occasions. Criteria have been changed when a good case for medical necessity has been made by organized groups of physicians and recognized by the federal authorities. This has occurred on several occastions because of the help of organized specialty sections in the state. Policies have also changed or been clarified beneficially when adverse effects of these policies have been recognized and solutions to problems created by the rigid regulatory requirements have evolved by innovative approaches.

Efforts to streamline the preadmission process and to computerize it have alleviated the need for an endless stream of written communications with physicians that would have taken far more of their time than the present system. In addition, efforts by those most familiar with coverage criteria have assisted physicians with their transition into the world of techno-bureaucracy they may not like but which in truth does exist.

The most difficult adjustment for all, however, has been the acceptance of the peer review organization as a professional organization performing review according to different sets of rules established by the purchasers of the peer review process. The concept that ground rules for federal review are different from private review for industry or IPA/HMO review for a group of physicians is hard to convey to physicians who feel that no review is

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necessary. The present reality is that review will simply not go away until the reasons necessitating the review go away.

Thus, the professional organization performs its task pretty much as an umpire or a referee might do depending on the game, and is subject to cries of "kill the umpire" or "kill the referee."

The peer review organization can survive this just so long as there is a need for it to perform and just so long as it is free to make comment on inequities in the system or gaps in the system as they are documented. This, CPRO has repeatedly done, but its influence is limited by its precarious position as the buffer between divergent forces. Nevertheless, it has carried its message to the profession, to the public, to the regulators and to the legislators with every means at its disposal. Close to one hundred presentations have been made in that vein over the past sixteen months by CPRO staff.

That message has detailed a reasonable and rational exposition of the accomplishments as well as the ill effects of coping with the need of insuring fiscal viability of the Medicare system by achieving a constraint of the system. There is no question but that constraint has ensued, but at what price?

After Congress approved a Medicare prospective payment plan for most in-hospital services in 1983, it became readily apparent that some of the perverse incentives inherent in the newly developed system required the emergence of a review body that would concentrate not only on unnecessary admissions, which triggered unnecessary payment, but that would also focus on changing patterns of care that might adversely affect the quality of care.

Although speculation about perceived effects was easy to evoke, factual material was hard to come by. Slowly, data has begun to emerge and conclusions with a basis in fact are surfacing. The answers to the most often asked questions are documentable.

Has a significant reduction in admissions to Connecticut hospitals taken place?

The projected *rise* in Medicare admissions to Connecticut hospitals in 1985 was purported to be between 3% and 5%. The actual decline, with exceptions, was actually 10%. This represents a 13-15% difference from the projected figure. One half of this figure (7,000 cases) represents a shift in cases to the ambulatory setting. (40% of surgery in 1986 is estimated to be on a one-day ambulatory basis). The other 7,000 cases represent patients not admitted to the hospital, but presumably treated in physicians' offices. Initial data run following initiation of the preadmission program indicates that an *additional* reduction has resulted from the preadmission program.

There is very little question that the health care system was being used for purposes other than medical necessity. There is also very little question that a certain laxness existed in overseeing the medical necessity for using the system and that over the years we grew accustomed to expect it. In addition, there is also very little question that the hospital was utilized as a societal support system. The ability to do so is now ending, however, many of the factors which prompted the system to be used in that fashion have simply not gone away. The need for external support still exists. These needs are now readily identifiable and efforts to document them in concrete fashion have begun. Providing the services needed will require a commitment to additional funding. As yet, no one can estimate whether the offset to the savings achieved by declining hospital admissions will be as costly, more costly or less costly than the previous system.

More important is the question of the quality of care that the citizens of Connecticut are receiving under a system which admittedly constrains services in hospitals.

By all objective criteria, nothing suggests any deterioration in the quality of care rendered by Connecticut physicians. Despite release of national mortality data that raised questions relative to a few Connecticut hospitals, case by case chart review has not revealed any evidence of the development of any pattern suggestive of a problem in that area. Nor is there evidence from the public health data in this state to suggest increased overall mortality rate by age groups.

Statistical data on readmissions casually related to premature discharge indicates that this eventually was noted in 0.3% discharges and that adverse effects from this have occurred in an even lesser percentage of cases. There is no comparable data to suggest what this incidence was before the prospective pricing system.

The independently funded and structured external audit initiated a few months ago by CPRO to track results of preadmission peer review determinations is in full operation. The preliminary data is supportive of the program, but far too sparse as yet for validity.

There is considerable evidence to support the contention that care is being rendered in this state that is effective, efficient and efficacious. These elements are the very basis of quality care.

The accessibility of affordable services must be documented and addressed. Society will best be able to deal with this when hard data are accumulated to support our contention that needs exist which must be met.

Profound changes are taking place rapidly in the health care delivery system. With these changes will come the final opportunity for physicians to control their own destinies and to control the quality of care their patients receive. In the coming environment in which this care will be rendered, the combination of cost effective and quality directed care will only be achievable if peer review is responsibly performed by a physician sponsored and supported organization.

Highlights of AMA Annual Meeting, June 1986

STEWART J. PETRIE, M.D.

On Sunday, June 15th the impressive ceremonies of the AMA were begun. The reference committees (of which there are eight and a committee on constitution and bylaws) debated vigorously on Monday the 16th.

While it is not possible to present many important resolutions and reports herewith, I have presented what seemed to me the more important items.

I. Committee on Constitution and By-Laws—the main action here dealt with the criteria for qualifying as a speciality section of the AMA. This chronic problem has lead to development of criteria for qualifications for a special section within the AMA. Definite criteria have been listed previously to qualify sections for membership with the AMA. These requirements, of course, include that a significant percentage (such as over 50%) meets such qualifications. The fact that they constitute a definite separate scientific entity and meet the designated number of times per year are some of the more important qualifications. This year we received applications from The American Academy of Child Psychiatry, The American Pediatric Surgical Association, The Renal Physicians Association (which were granted). Applications were also received from The American Association of Electromyography and Electrodiagnosis, The American Society for Dermatologic Surgery, The American Society of Maxillo-facial Surgeons and The American Association of Neuropathologists and The American Society of Bariatric Physicians (these were all not granted). Much testimony was received to the effect that many of these people are already represented in the AMA and the contention that it would add more members to the AMA by approving such organizations was held doubtful by many present. In any case, a moritorium was again put in place for admitting a new speciality section until the criteria is still further refined.

II. Reference Committee F. The main action here included the approval of formation of a young physicians section. (Board of Trustees report FF.) Despite the initial philosophic objection to presenting still a further section, an extremely good case was made by the younger physicians to the effect that they do indeed have some special needs which are not being met by the usual routes of the AMA. An excellent case was made to the fact that they were *not* well enough represented through the hospital medical staff sections and student and resident sections. They made a good case for the fact that they had some concerns which were not regularly faced by the older physicians. Furthermore, an excellent case was made for the fact that they would, indeed, increase the membership of the AMA. Details were well worked out by this group to avoid overlapping or interfering with the other actions of the AMA in general.

A report EE dealt with fiscal matters of the federation. Despite not being asked for any further dues increase, an effort was made by some present to give a small raising of the dues because of the fact that there was very little left for contingency funds in the forthcoming year. This was ultimately defeated.

The report KK of the Board of Trustees dealt with the "public awareness activities." This is an 18 page comprehensive report which lists the full gamut of activities which, when properly implemented, should increase public awareness of what organized medicine is attempting to do under the many headings of patient care. Some of the potential public awareness projects including 1) continue the present AMA initiatives, this is in the way of radio and TV commercials and "informercials," 2) issue oriented clearing house (which receives information from many sources and disseminates them for local usage to the local medical societies in particular or else to the public), 3) radio networking, 4) good doctor test (this is a self graded, self diagnostic test to let the physician know whether he or she is doing all that can be done to be responsive to the needs of the patients, 5) public service announcements, 6) AMA speakers bureau, 7) AMA Leadership programs, 8) creating state inventory of physician community leaders, 9) "meeting of the minds" (this is a pilot project to bring together older physicians and younger physicians for the purpose of exploring the practice of medicine and changing the environment), 10) an 800 number (Wats line). This is to respond to proactive or reactive calls each month from the media.

III. Reference Committee B. The major part of this committee dealt with tort reform and related issues. A newer concept was introduced regarding the use of "a clearing house." This is to provide all medical associations with a central repository of information concerning professional liability crisis. This would include information concerning legal challenges of the various tort reforms in the states etc.

The matter of child immunizations came in for a lengthy debate. This is due to the fact that immunization for children is mandated by many state laws (such as DPT immunization). On the other hand, product liability problems have led to the fact that there is now only one US producer making this vaccine. The great legal risk that this company is at, as well as the physicians in administering these mandated injections lead to concern here. A final

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resolution asks the AMA to increase the efforts to resolve the liability crisis in respect to childhood vaccines by urging congress to immediately enact tort reform which would allow for the safety, efficacy and availability of childhood vaccines at a conscionable cost.

IV. In Reference Committee C, physician manpower is dealt with chiefly from the Board of Trustees report Z. This is an 18 page report. This deals with the complex problem related to foreign medical graduates and their licensure as well as credentialing etc. Thirty recommendations are included in this report and was accepted as excellent work and outlines the role of the examining facilities and the FMG's in all aspects of their relationship to medicine and medical care in the United States.

V. Reference Committee A possibly one of the most important items in the entire meeting, report MM Board of Trustees. This is a 25 page extremely comprehensive report which deals with entirely new method of aiming toward preserving health care for the elderly, (rather than relying on the Medicare program which by any figures show it to be bankrupt in the future years). Recognizing the Medicare's serious limitations, it plans an attempt to correct these deficiencies by basing a new program on a set of actuarially and fiscally sound principles. Use of vouchers and a less than 1 percent point increase in payroll tax underlies the basis for this very extensively thought out program. It would be worthwhile for our membership to read this entire detailed report since it bears great hope and promise for the future.

The reference committee also dealt with many other matters of Medicare. The matter of mandated Medicare participation as a condition for licensure was a source of much concern amongst the membership. The AMA has reaffirmed its opposition to any such moves. Resolution 83 calls for the AMA to develop a mechanism to bring any necessary AMA expertise and funding to states facing mandatory assignment as a condition for licensure. It was viewed as a very serious matter which warrants priority attention of the federation.

VI. Reference Committee D. Several matters from hospital medical staff section were brought up especially in this reference committee. Reassertion of the fact that there should be a complete separation of authorities and responsibilities between hospital medical staff and its governing board. Dismissal of the CEO from the medical staff meetings was discussed with some of its ramifications. The limited experience with joint ventures was brought out (and was also addressed by Mr. McMahon of the American Hospital Association). The setting up of a liaison program with the boards of trustees at hospitals has been adopted and seems to be worthwhile measure.

The most interesting issue in this area, it seems to me, was regarding mandated professional liability insurance (as a condition for hospital appointment).

It was felt reasonable for hospitals to require this as a condition for appointment.

VII. Reference Committee E. The major direction of this committee report UU was the use of AMA facilities. It provides information on 1) the clinical spectrum of HTLV-III disease, 2) development of an AIDS vaccine, 3) therapy for AIDS, 4) AIDS-related viruses, 5) epidemiology of AIDS, and 6) an update on AMA's Action Plan on AIDS.

The AMA's Action Plan on AIDS includes a public information program that utilizes physician-education to address medical and social policy issues about AIDS at the community level. Health issues facing this country in regard to alcohol usage, smoking, physician suicide and hunger in America were all presented at this reference committee. (In regard to suicide, this was referred to the Board to explore the feasibility of developing a suicide prevention plan for physicians (including those in training).) In regard to hunger in America, the AMA reaffirmed its opposition to any further cuts in maternal and child health funding levels and to convene appropriate representatives to consider strategy stressing the problem of hunger in America.

VIII. Reference Committee G. This dealt with a large number of significant issues. There was a great fear amongst several organizations that capitation to fund a Champus program would be windowdressing for later attempts of the government to impose this program on all federally mandated health programs. After over one hour of heated debate, it was referred to the board (and the Board of Trustees will also receive the full nature of the many facets of this heated discussion to be included with their deliberations). The matter of whether a network of state wide IPA's could be administered from some central office was a featured point and subsequently received discouraging comments from the board etc. Several matters dealing with the administration of medical care by physicians was brought up in this committee. These included such matters as PRO problems, standardization of mandatory second opinion programs.

IX. Committee H touched on a wide variety of matters of narrow but nonetheless important issues. Emergency equipment to be carried on aircraft, dangers of tanning clinics, exemptions of physicians from jury service. Also the efforts given by the AMA in the matter of "missing and exploited children" outlined legislative initiatives, national programs, activities and other organizations. The report proposed physician involvement in the implementation here.

After this very full meeting with much heated debate, it would seem to this observer that the three most outstanding and different items were those of report MM dealing with this new program to supplant the Medicare program. The second report regarding the formation of a "Young Physician Section" should have farreaching and very beneficial importance to the AMA. The third most urgent matter dealt with the matter of restriction of freedom to contract under Medicare such as proposed by Massachusetts law (for acceptance of Medicare as a condition of licensure).

Chernobyl Nuclear Reactor Accident Pertinent Radiation Information: 1986

Even though a few months have gone by, many of your patients and friends may still be asking questions regarding the details of the Chernobyl accident. Does it effect our health at this time? How about travel to Europe following this accident? What are the possibilities of long range effects in this country from this accident? How can we continue the advantages of nuclear energy and nuclear medicine without risk to mankind? The following is abstracted from an extremely interesting journal supplied to the AMA House of Delegates from the American College of Nuclear Physicians.

For the interest of our readers a description of a nuclear reactor (and the one in Chernobyl in particular) is described and depicted. Included are several task force reports from the American College of Nuclear Physicians which were sent out regularly in the early times following the Chernobyl accident. This article concludes with a common sense discussion which is labeled "Measure for Measure." Although we can agree that eternal vigilance is the price of happiness, this article might help avoid the hysteria which is a natural phenomenon with such a disaster.

In the aftermath of the Chernobyl nuclear power plant disaster, the American Medical Association has formed a new committee to address the health problems associated with non-military radiation incidents, emergencies, and accidents. The Advisory Committee recommended the development of an action plan that would increase physician involvement at the community level, through state and county medical societies, and improve national recognition of physicians as expert resources for government agencies and the media. Among suggestions:

- State and county medical societies assist hospitals in developing emergency response plans.
- The AMA provide information packets to state and county medical societies.

On Friday, May 2, 1986, the American College of Nuclear Physicians (ACNP) held a news conference at the National Press Club in Washington, D.C. to attempt to clarify for the media what was happening after the nuclear accident at Chernobyl, U.S.S.R. Three nuclear physicians addressed the public health aspects of the radiation from the Soviet accident expected to reach the U.S., including information on long-term health effects, possible contamination of the food chain, and travel abroad.

Important Questions and Answers Regarding U.S. Health Risks Related To Soviet Nuclear Accident

Q: What is the danger of radiation in the United States from the Soviet accident?

A: Experts from the American College of Nuclear Physicians say radiation blown worldwide in the atmosphere posed no measureable health risk to the United States, based on what is known as of today, May 22, 1986. Long term health risks depend on the type of radiation Americans are exposed to. Cesium 137 and Strontium 90 were potential hazards, but only trace quantities have been carried in the atmosphere.

Q: What is this based on?

A: Predictions about possible health consequences of radiation exposure are based on follow-up of 60,000 irradiated survivors of the 1945 atomic bombings of Hiroshima and Nagasaki and numerous studies of purposeful above-ground weapons testing or accidental medical and/or occupational exposure to radiation.

Q: What is being monitored?

A: The disaster's dimensions will depend on the amount and type of radiation released, how long it was released, local weather conditions and world weather conditions. For example, if radioactive material passes through rain storms, the amount of radiation is further diminished. At this time, it does not appear that significant levels of radiation reached the U.S. from the Soviet accident. EPA and Nuclear Medicine physicians are continuing to monitor the atmosphere daily.

Q: What should Americans worry about in terms of their food supply, drinking water and health from the Soviet nuclear accident?

A: There is little likelihood that food and water in the U.S. has been affected. The radiation levels, based on current information, are too low. Food that is con-

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Abstracted by Stewart J. Petrie, M.D., Editor Pro tem from a report published by the American College of Nuclear Physicians, Washington, D.C.

taminated by radioactivity is easily detected, and federal authorities (EPA) are on the lookout for any potential problems with imported products.

Q: What are the long-term possible hazards for the U.S.?

A: Contamination of food or water by Cesium and Strontium. This has not occurred.

Q: How does this accident compare to Three Mile Island?

A: Three Mile Island, the United States' worst accident, was a contained accident; very little radiation was released. At Chernobyl, the Soviets use a different kind of nuclear plant construction and, unlike the U.S., do not have a secondary containment structure to trap the radiation as a safety backup.

Q: What could have been the worst case scenario?

A: The worst case from the standpoint of Americans could have been that the Soviet reactor(s) which burned out of control would continue to emit radiation over a long period. If that had happened, it is possible that slightly higher radiation levels might have been measured in the U.S. However, since the fire and radiation emissions were brought under control, the worst case did not occur.

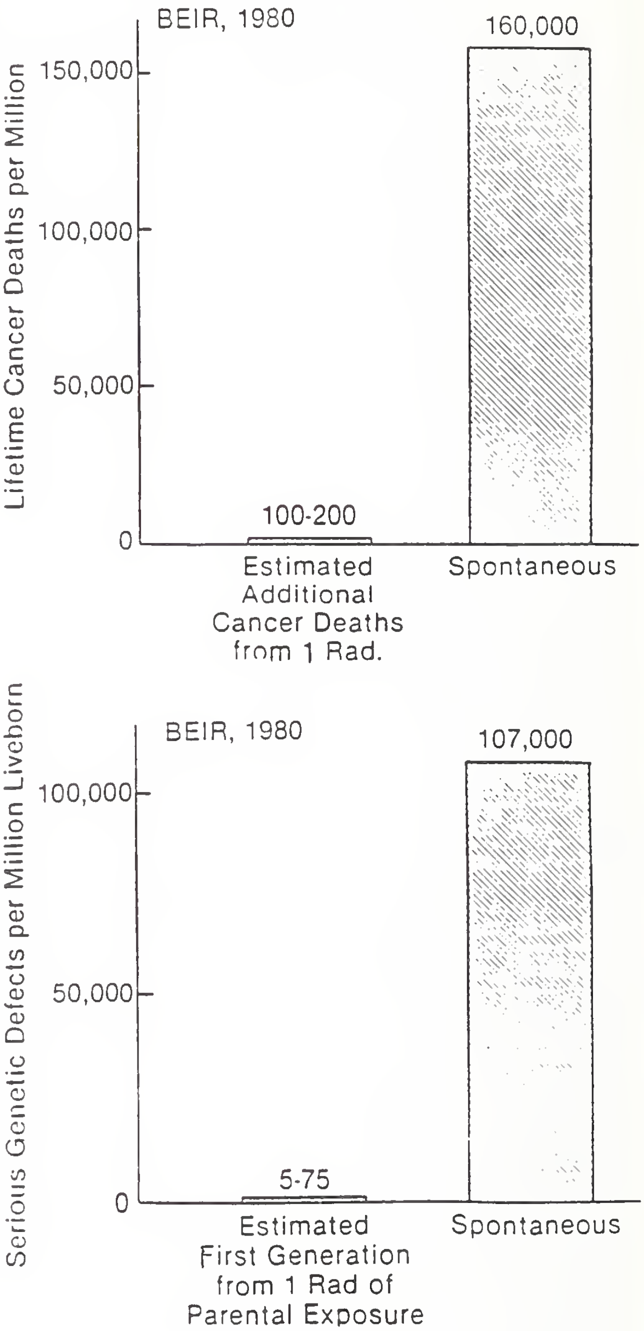
Risks that Increase Chance of Death by 0.000001[a]

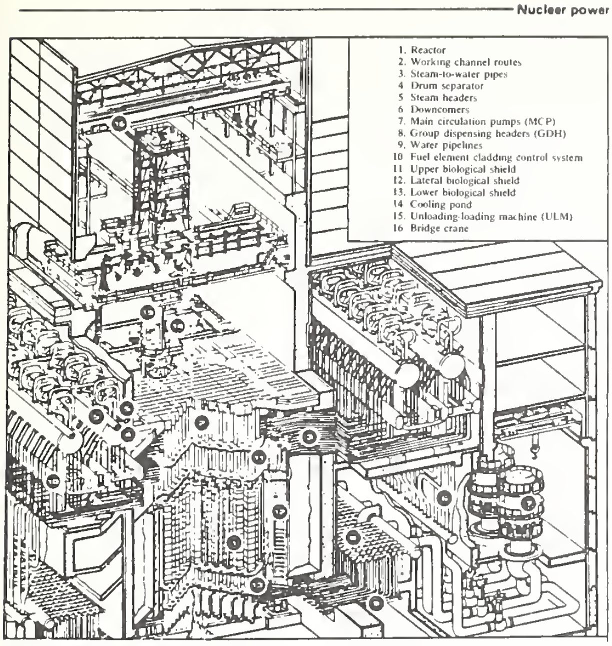
Smoking 1.4 cigarettes	Cancer, heart disease
Drinking ½ liter of wine	Cirrhosis of the liver
Spending 1 hour in a coal mine	Black lung disease
Spending 3 hours in a coal mine	Accident
Living 2 days in New York or Boston	Air pollution
Travelling 6 minutes by canoe	Accident
Travelling 10 miles by bicycle	Accident
Travelling 30 miles by car	Accident
Flying 1,000 miles by jet	Accident
Flying 6,000 miles jet	Cancer caused by cosmic radiation
Living 2 months in Denver	Cancer caused by cosmic radiation
Living 2 months in average	Cancer caused by natural radioactivity
One chest x-ray taken in a good hospital	Cancer caused by radiation
Living 2 months with a cigarette smoker	Cancer, heart disease
Eating 40 tablespoons of peanut butter	Liver cancer caused by aflatoxin B
Drinking Miami drinking water for 1 year	Cancer caused by chloroform
Drinking 30 12 oz. cans of diet soda	Cancer caused by saccharin
Living 5 years at site boundary of a typical nuclear power plant in the open	Cancer caused by radiation
Drinking 1,000 24 oz. soft drinks from recently banned plastic bottles	Cancer from acrylonitrile monomer
Living 20 years near PVC plant	Cancer caused by vinyl chloride (1976 standard)
Living 150 years within 20 miles of a nuclear power plant	Cancer caused by radiation
Eating 100 charcoal broiled steaks	Cancer from benzopyrene
Risk of accident by living within 5 miles of a nuclear reactor for 50 years	Cancer caused by radiation

Source: Wilson (1979), p. 45. (With permission from *Technology Review.*)

[a] One chance in 1 million.

Exposure to Small Amounts of Radiation: The Facts




Nuclear power
1. Reactor
2. Working channel routes
3. Steam-to-water pipes
4 Drum separator
5 Steam headers
6 Downcomers
7. Main circulation pumps (MCP)
8. Group dispensing headers (GDH)
9. Water pipelines
10 Fuel element cladding control system
11 Upper biological shield
12. Lateral biological shield
13. Lower biological shield
14 Cooling pond
15. Unloading-loading machine (ULM)
16 Bridge crane

A sectional view of the RBMK-1000 reactor. With an electrical power of 1000 MW, the reactor's thermal power is 3140 MW; the coolant flow is 37.5 x 10^3 t/h and steam capacity 5.4 x 10^3 t/h. the reactor inlet water temperature is 270°C and the saturated steam temperature 284°C with a pressure in the separator of 70 kg/cm^3. The initial fuel enrichment is 1.8%.

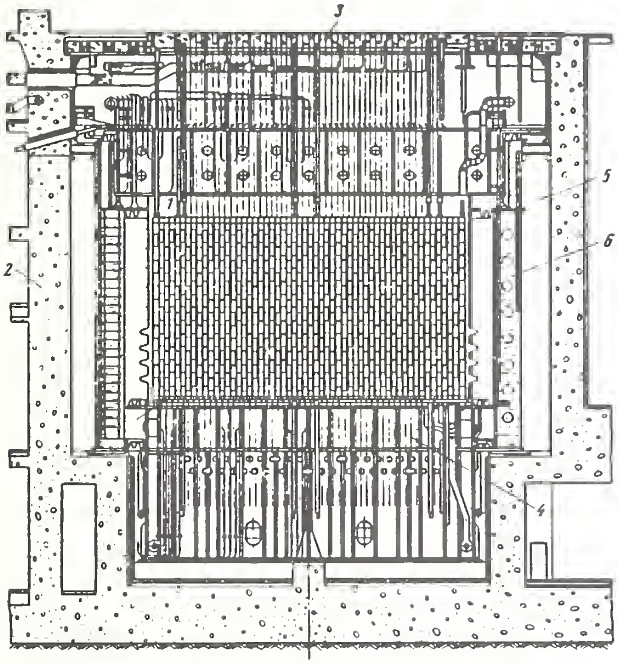


Figure 1-4
Cross-sectional view of an RBMK-1000 reactor station building (reactor shaft) 1—steel blocks; 2—ordinary concrete; 3—iron-barium-serpentinite-cement block; 4—serpentinite; 5—sand; 6—water

A Task Force Report
May 15, 1986

The EPA national monitoring network continues to detect radioactivity from the Chernobyl accident at various locations in the United States.

In samples analyzed at the EPA laboratory in Montgomery, Alabama yesterday, the first instances of iodine-131 detection in milk occurred. Iodine-131 was detected at identical concentrations of 26 picocuries (a picocurie is a trillionth of a curie) per liter (pCi/1) at two locations: Helena, Montana and Salt Lake City, Utah; samples from 28 other locations showed radioactivity not detected. These very low concentrations in milk pose no danger to area residents. For comparison, the U.S. Food and Drug Administration's (FDA) recommended Protective Action Guide for milk calls for preventive measures if the concentration reaches 15,000 pCi/1.

Air particulate samples analyzed yesterday showed very low levels of iodine-131 detected in fourteen samples from twelve locations, with values ranging from 0.15 picocuries per cubic meter (pCi/m3) to 1.6 pCi/m3. All other samples showed no increase above normal background.

Rainwater samples continue to show iodine-131 in many locations across the country. Nineteen samples out of 26 contained iodine-131 in concentrations ranging from 43 pCi/1 to 2400 pCi/1. Six of these rainwater samples were from Portland, Oregon. Samples collected in Portland over the last week have shown decreasing levels of radioactivity.

The range of air particulate values reported today is virtually identical to that reported yesterday. The rainwater values are about the same or slightly lower. However, since the pathway leading from rainwater to milk takes several days, it is expected that additional milk samples containing iodine-131 may be encountered, possibly at higher levels than those reported today.

May 20, 1986

EPA is aware of stories appearing yesterday from certain sources that fallout levels from Chernobyl in the United States are higher than previously reported. These reports are inaccurate. Levels of radiation being detected above background are extremely low, as EPA has been reporting all along. The EPA monitoring system is designed to detect potential threats from both radioactive particulates and gas. All detections to date are at levels so low that even the most sensitive portions of the population, including pregnant women and infants, face no significant health threat.

The readings above normal background being reported by EPA for the first time today are attached in the following tables. To help put the EPA readings in some context, please note that the Protective Action Guide (the federal level at which preventive measures would be taken) for "deposition" (a measure that combines the concentration of radiation in rainwater and the amount of rainfall) is 130,000 pCi/m2 for Iodine-131; and the Protective Action Guide for milk is 15,000 pCi/1 for Iodine-131.

All readings are far below levels harmful to human health.

EPA Statement

The U.S. Environmental Protection Agency has issued the following statement about the Russian reactor accident:

Based on the latest data that has been gathered since we learned of the accident, it appears that the radioactive air mass from the Chernobyl nuclear reactor accident in the Soviet Union is currently moving northeast over the Soviet Union. During the next few days it is expected that the air mass will be dispersed by normal atmospheric activity. It is too early to determine whether any portion of the radioactive air mass will reach the continental United States. From the limited information we now have, should any radiation reach the U.S., it is highly unlikely that it would be at a level that would pose any threat to public health. This is because of the dispersion which would take place in the atmosphere.

The Environmental Protection Agency, which maintains the nation's radiation monitoring network, has increased sampling frequency to a daily basis for airborne radioactivity.

The White House has established an interagency task force to coordinate the government's response to the nuclear reactor accident in Chernobyl. The task force is under the direction of Lee Thomas, administrator of the Environmental Protection Agency, with representatives from appropriate federal agencies. It will provide continuous monitoring of any health and environmental implications resulting from the Chernobyl accident. EPA will provide daily press briefings based on the information gathered by this task force.

Information available as of April 29th indicates the Soviet reactor accident occurred in the fourth, and newest, reactor of the Chernobyl nuclear power station. This reactor is a graphite-moderated, pressure tube reactor of a type called RBMK by the Soviets. The reactor suffered a major accident, including a fire in the graphite core. Given the amount and extent of the radiation release, the fire has destroyed most of the reactor's core. The reactor core contains approximately 200 tons of uranium interspersed within 1,700 tons of graphite. The fire will continue to spread radiation from the core as long as it burns, although the Soviets have indicated that the rate of release is decreasing.

For the latest tape recording of information, call 301-652-1078.

To contact an AIF staffer outside of working hours, call 301-986-1535.

The following information on the Russian RMBK-1000 reactor has been compiled from *Construction of Nuclear Power Plants*, edited by Professor V. Dubrovsky, D.SC. (Eng.), 1979 (translated into English in 1981), MIR Publishers, Moscow; and "Graphite-Water Steam-Generating Reactor in the USSR" by N.A. Dollezhal (member of the Academy of Sciences of the USSR) in *Nuclear Energy*, 1981, Vol. 20, No. 5.

The reactor is referred to as a RBMK-1000. The 1000 denotes the 1000 MWE capacity. The RBMK means "high power pressure tube reactor." It is also referred to as a light-water cooled, graphite-moderated, pressure-tube reactor, a channel-type graphite-uranium boiling-water reactor, or a water-graphite reactor.

The core arrangement is a rectangular array. The core is cylindrical with an equivalent diameter of 12.2M and a height of 7M. It is enclosed by a radial reflector 1M thick and top and bottom reflectors 0.5M thick. It contains graphite bricks (250 x 250MM) that are stacked with a vertical hole through them.

The pressure-tubes (containing the fuel) run through some of these vertical holes. Other holes accommodate control rods and instrumentation.

The 2488 graphite stacks are contained in an air-tight vessel (reactor space) filled with an inert gas (helium and nitrogen mixture) at a pressure close to atmospheric.

The core sits on welded metal structures which act as biological shields and transfer the weight of the core to a bottom support slab made of concrete.

A top slab of concrete similar to the bottom support slab rests on a water-filled tank which provides a thermal (heat) shield for this concrete which acts as a biological shield (shielding radiation).

The coolant supply system includes coolant headers (manifolds) located between the reactor section and the roof. The steam that runs the turbine is produced in the core, in the pressure tubes. The headers carry the steam-water mixture to steam separators.

The separators remove any water from the steam before the steam goes to the turbogenerator. The water is returned to the bottom of the pressure tubes via downcomer pipes. The RBMK differs from U.S. systems in that it involves 1661 separate steam/water tubes rather than the single large reactor-vessel with large pipes that carry water into it and either steam or water out of it.

The pressure tubes pass through the space occupied by the coolant supply system headers and terminate in refuel heads. The refueling mechanism sits on the roof of the reactor section. Refueling can be accomplished on-line (during reactor operation) by depressurizing individual tubes.

Each pressure tube contains a fuel assembly holding two sub-assemblies, one above the other, each about 3.5M long. There is a gap of about 20MM between the two sub-assemblies. Each sub-assembly consists of 18 fuel elements which have zirconium alloy cans containing uranium dioxide pellets 11.5MM in diameter. The uranium is enriched to 2% uranium-235.

The control rod drive mechanisms are located below the reactor section. There are 211 control rods which have a separate water circuit for cooling them.

The zirconium pressure tubes in the RBMK are a once-through system. (Older models used both evaporating and superheating channels made of stainless steel.)

The Chernobyl plant utilizes two 500-MW turbogenerators.

Americans returning from countries affected by the Chernobyl accident may have concerns regarding their possible exposure to radioactive fallout during their travel. The data presently available show that travelers in some areas, near the Chernobyl site, have inhaled or ingested radioactive material in detectable amounts, but amounts not considered to be of health concern.

The likelihood of a health problem is minimal. Nevertheless, U.S. citizens returning from travel in the USSR that occurred during the period April 26 through May 31, 1986, and that was within 250 miles of Chernobyl, and who are concerned, may wish to have an evaluation of possible radiation levels by submitting to a measurement of residual activity in the thyroid at a nuclear medicine laboratory. This test is simple, requires no preparation, does not involve additional radiation and can readily be arranged through one's personal physician.

Concerned travelers who intend to have the test should not delay in obtaining this test because iodine-131 levels in the thyroid decrease rapidly in a period of days due to radioactive decay and accurate evaluations become more difficult. Persons who are found to have some residual I-131 activity are advised that there is no drug or therapy which would be helpful in reducing the dose. Potassium iodide (KI) is not effective in reducing the dose after the radioactive iodine has reached the thyroid.

The question has been raised whether American citizens touring Europe for several weeks following the Soviet accident should seek medical screening procedures from United States military hospital facilities there.

The Public Health Service does not recommend such screening on a routine basis. Rather, upon return, if they have concerns, travelers should obtain information and answers to their specific questions by contacting their State Radiation Control Program (located either in their State Health Department or State Environmental Protection Agency) or from their physician.

The Task Force reiterates their earlier advisory that the levels of radioactivity expected to reach the ground in the U.S. are considered to be no health threat and recommends against the taking of potassium iodide (KI) to minimize the uptake of radioiodine.

Man-Made Radiation

Individuals also receive radiation doses as a result of the use of man-made radiation and radioactive materials for various purposes. Such doses result from additional exposures to exactly the same kinds of radiation found in nature. Many people are exposed to radiation for medical reasons, for example. In 1970, an estimated 212 million x-ray examinations were performed in the United States. The dose to the skin from one chest x-ray is usually in the range of 0.03 to 0.05 rem, and the average dose to the skin from an abdominal x-ray is about 0.6 rem. X-rays are also used extensively, of course, for dental examinations. The radiation dose to the skin from one dental x-ray is about 1 rem. In all, radiation used for the purpose of medical diagnosis accounts for about 90 percent of the total man-made annual radiation dose received by the population of the United States.

Radiation: Measure for Measure
The Common Denominator

Americans keep driving—to work, on errands, for pleasure. Many relax by swimming or boating. And travel by airplane.

These activities continue despite general awareness that some 50,000 people are killed in traffic accidents each year. That nearly 6,000 persons drown. More than 1,500 deaths are caused by aircraft crashes.

Immediate and visible in their impact, these dangers are concrete, familiar; society accepts them almost routinely. As a result, thousands of lives most likely will be lost this year from similar sources.

At the same time, many people express concern over nuclear energy—about reactor safety, fuel shipments, waste disposal—based primarily on fear that radioactive materials may be released, that radiation might harm residents of surrounding communities.

This alarm remains even though, during two decades of commercial nuclear power in this country, not a single death from radiation ever has been observed among the public—even at Three Mile Island. And the likelihood of such a fatality taking place in the future is very small.

Radiation, then, arouses anxiety more for its *potential* risk than for its *actual* hazard; a force considered new, unknown, escaping the senses and causing unique injuries which may not appear for many years.

In fact:

- Radiation from a nuclear power plant is identical in physical behavior, identical in effect on man, to that already and always existing in nature.
- Radiation produces no biological damage that does not occur also from other natural, physical and chemical causes.
- Radiation after more than 80 years of intensive study is the most scientifically understood, easily detected, precisely measured, effectively controlled and strictly regulated of all environmental agents.

Examining the sources and amounts of radiation encountered in everyday life, analyzing and comparing their potential contribution to excess health effects, will lead to further understanding and realistic perspective on this compelling, fundamental issue.

Sum of Many Parts

From cosmic rays and the sun; from deposits of uranium, radium and thorium in the earth's crust; from radon in the air and radioactive potassium in food and water, man has been surrounded by radiation since time began. Today these naturally occurring sources expose an individual in the U.S. to an average dose of about 100 millirem each year.

A *millirem* measures radiation's biological effect, as degrees gauge temperature or inches, distance.

This environmental radiation varies widely, depending primarily on altitude and concentration of radioactive minerals in the ground. On coastal plains, such as in Florida, the typical dose per person is about 70 millirem annually; on mountain plateaus, such as in Colorado, approximately 165 millirem each year.

Remaining the largest share—about half—of man's total annual exposure, little can be done to reduce this inevitable natural background radiation. Just the *variations* in dose from place to place—among which no difference in number of health effects ever has been established—exceed by far routine public exposures from any industrial activity.

Of the radiation contributed by man's technology, most comes from the use of X rays and radioactive materials in medical diagnosis and therapy; an average individual dose per year of about 90 millirem.

Mining minerals, burning fuels, building structures and other social actions which redistribute natural radioactive elements; fallout from past testing of nuclear weapons; consumer products such as color television, smoke detectors, luminous dial watches and miscellaneous sources add approximately 10 millirem each year.

Finally, from routine operation of all commercial nuclear power plants and all the facilities in their fuel cycle, the calculated average annual dose to an individual in the domestic population today is about ⅓ of one millirem.

Nuclear energy, then, is only one—and among the least—of the many sources of radiation present in society today. Without nuclear electricity, the average American now receives about 200 millirem annually. With nuclear power, approximately 200.3.

Biological Effects of Radiation

Very large amounts of radiation—far above the levels found in daily life—can result in early death or delayed injury, principally cancer and genetic defects.

Convincing medical evidence that radiation increases the normal chance of eventually developing cancer comes mostly from the few groups of people—pioneers in medical radiology, patients treated with X rays, victims of Hiroshima and Nagasaki—subjected to massive doses—from tens of thousands to millions of millirem—usually in one or a few incidents.

Many more people have been studied extensively over several decades to determine if a link exists at lower levels of exposure. Below about 10,000 millirem, all experience with human adults generally has been negative.

Hereditary illness related to radiation has been observed only in laboratory experiments with animals. Although it is prudent to assume that similar damage may take place in man, none ever has been discovered—even at extremely high doses.

Both these injuries associated with radiation cannot be distinguished from those occurring naturally and caused by other factors; further, they may not develop for several decades after the exposure assumed to produce them. At typical natural and technological doses, therefore, a population of hundreds of millions would have to be carefully investigated for many years to reveal any significant—statistically apparent—increase in fatal cancers or inherited disorders.

That health effects at relatively low levels of radiation are too small or occur so rarely to be detected may be part of the problem—*but it is also part of the solution.*

The ACNP Speakers Bureau can schedule nuclear physicians to address the subject of radiation at your meetings. For further information please contact Barbara Teele, Program Coordinator, ACNP, 1101 Connecticut Avenue, N.W., Suite 700, Washington, D.C. 20036, (202) 857-1191.

CSMS SEEKS IPA-MEDICAL DIRECTOR

CONNECTICUT STATE MEDICAL SOCIETY (CSMS) – INDIVIDUAL PRACTICE ASSOCIATION (IPA) SEEKS A PHYSICIAN INTERESTED IN ORGANIZING IPA COMPONENT OF STATEWIDE HMO. CANDIDATE MUST HAVE KNOWLEDGE OF QUALITY ASSURANCE AND UTILIZATION REVIEW SYSTEMS IN PREPAID ENVIRONMENT. SALARY COMMENSURATE WITH EXPERIENCE. PLEASE SUBMIT CURRICULUM VITAE TO IPA SEARCH COMMITTEE AT CSMS, 160 ST. RONAN STREET, NEW HAVEN, CT. 06511.

Hospital Privileges: Speak Softly, But Carry A Big Lawyer

ARTHUR R. CHENEN, J.D.

Diplomacy is often more effective than firepower. Here's expert advice on when to be cooperative and when to be combative.

A physician recently came to me terribly upset. He'd been ill and out of practice for a year, and now was well enough to resume work. However, his hospital wanted proof that he still had all his medical skills.

"That not only impugns my integrity and reputation," he declared, "it's an intrusion on my privacy. I've been on that staff for 15 years without one black mark against me. I'll fight this in court if necessary."

I tried to calm the doctor by clarifying two important points for him:

First, I noted, during the year he'd been out of practice, courts repeatedly had emphasized that hospitals have a corporate responsibility to assure the competence of their medical staff members. "So if something did go wrong on one of your cases, and you and the hospital had to go to court," I said, "the plantiff's attorney could say to the hospital, 'Hey, this guy was gone for a year, and you let him come back without proper check on his competence and his health.' The hospital wouldn't stand a chance—and neither would you."

Second, I pointed out, the hospital had a primary duty to protect patients from harm. "You also have that duty, and your record shows you've lived up to it," I reminded the doctor. "By going along with the hospital, you'll be protecting that record and acting in your own best interest."

The doctor finally agreed, and we worked out with the hospital a temporary monitoring program—which, incidentally, has just ended satisfactorily for all concerned.

The moral: Don't overreact if your privileges are threatened. Many doctors, I've found, react with anger or fear. As a result, they tackle the problem irrationally, rather than reasonably. Take the time—and seek the necessary advice—to evaluate and deal with the problem.

Don't Underreact

Many doctors submit to what they think is a minor restriction on their privileges without questioning it, figuring, "No big deal."

Don't be too sure. There may be repercussions you can't anticipate. Example:

An ophthalmologist was informed that the complication rate in some of his cases was slightly high, and it was suggested that his next three procedures be monitored. He didn't object.

Months later, two other hospitals where he had privileges notified him that renewal was being held up because he'd been "disciplined" at hospital *x*. He also found out that the "disciplinary" action had been reported to the state agency responsible for policing doctors—the first blot on his record. On top of that, his referrals and income were dropping drastically because word of the action against him had gotten around.

The GP resigned before the peer reviewers could pass judgment on him. If I'd known of the basic flaw in his defense, I might have gotten him off with a stipulation that he call in consultants promptly.

Only then did the doctor come to me, wanting to know what to do. At that point, there was nothing that could be done about the primary problem, the restriction on his privileges. He had complied with it, and the time for appeal was long past.

I did find out, though, that the disciplinary action should *not* have been reported by the hospital. It was not a significant action that had lasted more than 45 days and so, under California law, it wasn't reportable. Consequently, I was able to have the report expunged from the state

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disciplinary agency's files. On behalf of the ophthalmologist, I've also filed suit for damages against the reporting hospital.

All this probably could have been averted if the ophthalmologist had questioned the restriction in the beginning, thus clarifying the matter for himself and the hospital.

Know Your Hospital's Bylaws

Many doctors don't bother to read their hospitals' bylaws—or, if they do, they don't understand them. So when trouble crops up, they don't know their rights.*

A cardiologist contacted me because he was threatened with dismissal from his hospital staff. After studying the problem, I saw it was basically a personality clash with his department head. Yet, because the cardiologist hadn't read the staff bylaws, which spelled out very specifically the reasons for which a doctor could be thrown off the staff, he feared he was in big trouble.

The whole thing was straightened out in a simple staff conference. In essence, the cardiologist and the department chief agreed to stop provoking each other.

Lesson: Staff bylaws are your first line of defense in any privileges battle. Make sure you understand them.

If You've Made a Mistake, Admit It

It was a serious case. An internist had left a hospitalized patient to attend a basketball playoff game out of town. During his absence, the patient took a turn for the worse. The chief of the department had to take over, and he was hampered by a lack of up-to-date progress notes. It looked as if the attending physician would, at the very least, lose his privileges.

However, he made exactly the right move. He immediately presented himself before the peer review committee and stated: "I made a mistake. Please let me explain."

It then became clear that (1) the internist, a popular doctor who couldn't say No to a new patient, had overloaded himself; (2) because his chief office assistant was ill, he'd fallen behind in his record-keeping; (3) he'd spent five straight hours in the hospital with the patient in question, and had left only when it appeared the medical problem was under control; (4) he'd arranged for coverage, but that doctor unfortunately was busy with a patient of his own when the call from the hospital came in; (5) the internist had never before been disciplined; and (6) the patient had suffered no lasting harm.

Result: The physician was let off with relatively light sanctions. He was ordered to keep his records up to date, and to hold his patient load to a reasonable level.

Admitting a mistake usually relieves the tension between the accused physician and the peer reviewers. They understand mistakes; they've made a few themselves.

Get an Objective Opinion

I learned about this the hard way. One of my earliest doctor clients was an older general practitioner who retained me to represent him in a privileges fight. He had an excellent reputation, the only GP in his hospital to hold OBG privileges. Now the hospital wanted to revoke them and turn them over to a board-certified obstetrician.

The GP had a very authoritative manner, and he convinced me he was absolutely in the right. During the peer review proceedings, however, the hospital called in outside medical experts who identified cases where he'd waited too long before calling in consultants.

The GP resigned before the reviewers could pass judgment on him. If I'd known of the basic flaw in his defense, I might have gotten him off with a stipulation that he call in consultants promptly under certain circumstances.

More recently, an internist came to me after he'd been accused of faulty reading of X-rays. I brought in two radiology experts who agreed there were some mistakes, but they were within the acceptable range.

Moreover, I discovered, the cases against the internist had been picked out selectively rather than randomly by the hospital radiologist, who'd had some disagreement with the internist and investigated the basic charge against him. When I suggested to the radiologist that we be allowed to select some of *his* cases and see how they compared with the internist's, the charge disappeared.

Know When to Compromise

Very often staff physicians get into trouble because they try to do more than they're really able to do. A case in point:

A family practitioner had been practicing in a northern California hospital for 35 years when, partly because of his advancing age, questions were raised about his general capabilities. Peer reviewers found he was doing fine except in obstetrics, where a report stated, "He really is not performing at community standards today."

On behalf of the doctor, I worked out a compromise with the hospital: He voluntarily relinquished his privileges to deliver babies and was allowed to retain all others.

In another case, a general surgeon was performing 15 different procedures at a certain hospital. A review of his work showed that he was having trouble with two of them, and he was given notice that his privileges were under scrutiny.

At first, he wanted to fight. "They'll probably want to monitor me," he said, "but I won't put up with that."

I asked him how often he performed the two procedures in question.

"A few times a year."

Then, I pointed out, he didn't really need those particular privileges. Wouldn't it make sense to give them up and hold on to the ones he did most often? He agreed it would, and that was the basis for a compromise we

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*See "Your Surprising Ally in a Privileges Fight," *Medical Economics*, June 10, 1985.

reached with the hospital: He wouldn't do the two procedures, and they wouldn't monitor the rest of his work.

Peer reviewers don't like confrontations. The anger takes a lot out of everybody, and usually aggravates rather than eases problems. Seek compromise.

Consult a Lawyer Early

A phone call I received not long ago is typical of many I get from doctors: "They're throwing me off the staff of my hospital."

"You mean you've received notice they intend to initiate action against you?"

"No, the governing board has acted and I'm off the staff. What can I do?"

The only answer at that point is: Sue, if you can. The damage has been done.

Let me clarify a particular point here. If you're trying to *obtain* hospital privileges, don't immediately bring in a lawyer—that can turn the application process into an adversarial one.* But if you're trying to *retain* your privileges, the situation is adversarial from the start. Points of law are involved, so get legal advice as soon as you receive notice of possible action. And go to a lawyer who's knowledgeable in hospital law. Your local bar association or medical society can probably give you a referral.

Another good reason not to wait too long for legal advice: You might be trapped into summary suspension. Hospitals are becoming increasingly aggressive in their disciplinary actions, not only against incompetent doctors but also those who simply displease them. Rather than spend a lot of time and money in getting rid of an unwanted doctor, they summarily suspend him.

In doing that, though, they may be acting illegally. Basically, a medical staff member can be summarily suspended only if his presence in the hospital constitutes an immediate threat to patients. A good lawyer can tell you at once whether a summary suspension is justified—and possibly save you from having to battle your way back in.

Don't Start a Fight You Can't Finish

If you're unable to resolve a privileges dispute through compromise or negotiation, you face a big question: Shall I mount a full-scale war?

If you know you're in the wrong, you'd probably be better off to cut your losses and make the best of it. If you're right, of course, and you have a good case, gird for combat.

Before you do, though, make sure you're willing and able to go the whole route. Consider these four points: (1) The process can be long and arduous, both in the hospital and in the courts. (2) It can be emotionally and financially exhausting. (3) At some point, the records may become public, bringing unwanted attention. (4) Under most bylaws and in most courts, the accused doctor has the burden of proving he's right—unlike a criminal trial, where you're presumed innocent until proved guilty. I've seen more than a few doctors give up.

Some of those doctors made the mistake of relying on the medical staff for help. As one surgeon told me, "They're my friends—they'll support me."

Maybe they were his friends, but they didn't support him—for two reasons: They were in competition with him for referrals, and they were unwilling to antagonize a powerful department chief who wanted the accused doctor off the staff.

As I always caution my doctor clients: "Medical staff support may be a mile wide, but it's usually only an inch deep. Don't count on it."

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*See "Ways You Can Win the Privileges Game," *Medical Economics*, Sept. 23, 1985.

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Single Dose Cefazolin For OB/GYN Surgical Prophylaxis

KAREN SMITH, R.Ph.

Surgical Prophylaxis

Surgical procedures carry a significant risk of post-operative site infection which, for the most part, can be prevented by pre-operative antibiotic prophylaxis.[1] In OB/GYN surgery, vaginal hysterectomies are at a higher risk for bacterial contamination, and infectious complications are more likely to occur if antibiotic prophylaxis is not provided.[2] Post-operative infections from cesarean sections and abdominal hysterectomies are less common and usually only patients at high risk for infection require prophylactic antibiotics. These risks include prolonged labor, rupturing of membranes, excessive blood loss, and/or anemia, increased duration of procedure, patient obesity, and use of general anesthesia.[1,2]

The timing of prophylactic antibiotic administration is critical. Burke et al. demonstrated in a classical animal study that a significant decrease in lesion size resulted when the antibiotic administration is timed closely to surgical contamination.[3] He feels that antibiotics *must* be given preoperatively in close proximity to the time of surgery so that tissue concentrations are maximized. Several other authors agree with these recommendations.[4,5,6] Burke also reported that antibiotics delivered 3-4 hours after the surgical procedure are not effective for prophylaxis.[3]

Microbiology Considerations

Ordinarily, common pelvic pathogens that cause infectious complications are endogenous anaerobic organisms such as anaerobic gram-positive cocci, and *Bacteroides* species (other than *B. fragilis*). *E. coli, B. fragilis, Enterobacter* species and *Enterococci* are less frequently found; but appear in the post-operative period after vaginal operations. These organisms are also the primary contaminants of abdominal gynecologic procedures.[9] Most strains of *S. epidermidis, Strep.* species, *E. coli, Klebsiella* species, and *Proteus* species are susceptible to cefazolin, while *B. fragilis* and other anaerobes are moderately susceptible.[8]

Pharmacokinetics of Cefazolin Relevant to Prophylaxis

Cefazolin is an ideal choice for antibiotic prophylaxis during OB/GYN surgery, since it is effective, well tolerated, inexpensive, and has relatively long half-life ($t_{1/2}$ of 1.8 hours). A 1 gram dose of cefazolin administered intravenously provides serum levels of 107-185ug/ml and 70ug/ml at 30 and 60 minutes after dosing, respectively.[19,20] Since the elimination half-life of cefazolin is 1.8 hours, the serum levels remain above 2ug/ml for approximately ten hours. Such concentrations are more than adequate to cover most susceptible organisms as the minimum inhibitory concentration (MIC) for most organisms susceptible to cefazolin is less than 2ug/ml.[8]

Cefazolin tissue levels have been shown to peak 25-40 minutes after administration of a single 2 gram intravenous dose.[7] In this study by Yamada et al., peak endometrium levels were 98.9ug/gm, myometrium levels were 109.5ug/gm, and perimetrium levels 154ug/gm. These tissue levels were maintained over 12.5ug/gm for at least 150 minutes.[7]

Clinical Efficacy

A number of authors suggest that single-dose cefazolin should be more than adequate for surgical prophylaxis.[4,6,12,13] Two studies demonstrating the effectiveness of single-dose cefazolin therapy are reported in the literature. The first study was an animal study comparing prophylactic use of single-dose cefazolin to multi-dose cefazolin, to single and multi-dose cefonicid, and to placebo. All four treated groups had significantly less wound bacterial contamination than the control, but none of the treated groups differed significantly from each other.[14]

The second study was randomized, triple blinded, prospective clinical study in which patients were given 1 gram cefazolin as a single intramuscular dose prophylactically, multi-dose cephaloridine, or placebo. The treated groups were similar with respect to length of hospital stay and infectious complications such as febrile morbidity, septicemia, and urinary tract infections. The control group had a significantly higher incidence of these complications than either of the treated groups.[5] Two other clinical case studies using single-dose prophylaxis of other first-generation cephalosporins support these findings.[4,15]

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This new series on Drug Information Updates from the Hartford Hospital are supplied by Charles H. Nightingale, PH.D., Director of Pharmacy Services, Hartford Hospital.

There are other studies which demonstrate that multi-dose cefazolin is equally effective to multi-dose cefoxitin in preventing infectious complications in gynecologic surgical procedures.[13,16] Also, many studies exist comparing cefazolin (or other first generation cephalosporins) to other prophylactic antibiotics. All confirm that cefazolin is as effective as any of the other agents used.[4,11,22-29]

Cefazolin has been well tolerated as a prophylactic antibiotic in most of the reported case studies. There has been only one reported case of pseudomembranous colitis associated with *Clostridium difficile* which developed three days post C-section. The patient had received 1 gram of cefazolin pre-operatively.[10]

Recommended Therapy

Antibiotics needed to combat resistent infections should be reserved for therapy and not used for prophylaxis (i.e. aminoglycosides for serious gram negative infections, clindamycin for infections due to anaerobes such as *B. fragilis*).[6,11,12] Cefazolin is generally not a first-line therapeutic antibiotic in infectious complications, and therefore is a useful prophylactic agent in most instances. Exceptions to this are patients who have possible allergies to cephalosporins, or patients who are at risk for developing endocarditis. In these patient groups, the prophylactic regimen should be targeted toward prevention of infection due to enterococci. The current recommendations are use of an aminoglycoside combined with ampicillin.[21] Patients who are allergic to penicillin (e.g. anaphylaxis, major uticaria) should receive alternate therapy, such as vancomycin.

The Division of Infectious Disease at Hartford Hospital recommends the use of single-dose 1 gram cefazolin for OB/GYN surgical procedures (i.e. vaginal hysterectomy, abdominal hysterectomy, C-sections). This recommendation was approved by the Therapeutics Committee and supported by the Department of OB/GYN. Due to logistical problems of administering the prophylactic antibiotic 1 hour prior to surgery, the antibiotic is given at the time of induction of anesthesia or after clamping the cord for C-sections. In view of the fact that cefazolin is much less expensive than other cephalosporins, considerable cost saving is anticipated if single dose cefazolin prophylaxis is used. (Table 1).

Summary

The use of single-dose 1 gram cefazolin should be effective prophylactic regimen in most OB/GYN surgical procedures with a significant cost savings to both the patient and the hospital. In patients who are at a high risk for developing endocarditis, the prophylactic use of an aminoglycoside combined with ampicillin is preferred. Patients who are allergic to penicillin should receive vancomycin instead of ampicillin.[21]

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Table 1
COST OF SINGLE AND MULTIDOSE PROPHYLACTIC ANTIBIOTIC THERAPY AT HARTFORD HOSPITAL

	Dosing Regimen		*Antibiotic Cost*	*Cost of Administration**	*Total Cost*
Cefazolin	1 gram	1 dose	$ 3.14	$3.43	$ 6.57
Cefazolin	1 gram	3 doses	$ 9.42	$7.17	$16.59
Cefoxitin	1 gram	1 dose	$ 7.42	$3.43	$10.85
Cefoxitin	1 gram	3 doses	$22.26	$7.17	$29.43
Cefoxitin	2 grams	3 doses	$42.51	$7.17	$49.68
Cefuroxime	1.5 grams	1 dose	$11.25	$3.43	$14.68
Mezlocillin	4 grams	3 doses	$27.60	$7.17	$34.77
Cefotetan	1 gram	1 dose	$ 7.80	$3.43	$11.23

*includes daily supply cost, cost of administration sets, cost of nursing administration time, and cost of pharmacy technician time.

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Alcohol and the Driver

AMA COUNCIL ON SCIENTIFIC AFFAIRS

Scientific investigations have produced 50 years of accumulated evidence showing a direct relationship between increasing blood alcohol concentration (BAC) in drivers and increasing risk of a motor vehicle crash. There is scientific consensus that alcohol causes deterioration of driving skills beginning at 0.05% BAC or even lower, and progressively serious impairment at higher BACs. Drivers aged 16 to 24 years have the highest representation of all age groups in alcohol-related road crashes; young drivers involved in alcohol-related fatal crashes have lower average BACs than older drivers. Alcohol impairs driving skills by its effects on the central nervous system, acting like a general anesthetic. It renders slower and less efficient both information acquisition and information processing, making divided-attention tasks such as steering and braking more difficult to carry out without error. The influence of alcohol on emotions and attitudes may be a crash risk factor related to driving style in addition to driving skill. Biologic variability among humans produces substantial differences in alcohol influence and alcohol tolerance, making virtually useless any attempts to fix a "safe" drinking level for drivers. The American Medical Association supports a policy recommending (1) public education urging drivers not to drink, (2) adoption by all states of 0.05% BAC as per se evidence of alcohol-impaired driving, (3) 21 years as the legal drinking age in all states, (4) adoption by all states of administrative driver's license suspension in driving-under-the-influence cases, and (5) encouragement for the automobile industry to develop a safety module that thwarts operation of a motor vehicle by an intoxicated person.

Three resolutions relating to alcohol and driving were referred to the Board of Trustees at the 1984 Annual Meeting of the House of Delegates. The House requested that a comprehensive report on alcohol and its effects be prepared for the 1985 Annual Meeting.

Resolution 18 called for the American Medical Association (AMA) to study methodology intended to deter the use of an automobile by an intoxicated person. Resolution 64 asked the AMA to urge Americans to refrain from driving under the influence of alcohol, asked the AMA to conduct an education campaign on this subject, and asked the AMA to support mandatory suspension of a driver's license for one year for any conviction for a moving violation if any alcohol is found in the driver's blood. Resolution 83 urged an AMA study of recent legislation among the states on driving while impaired, with incorporation of the effective elements into model legislation for distribution to the membership.

In addressing the concerns cited in the resolutions, reviews were undertaken of current literature on (1) the relationship between blood alcohol levels and driver impairment, (2) scientific issues regarding the reliability of methods to test blood alcohol levels in drivers, and (3) alcohol-impaired driving countermeasures.

Epidemiology of Alcohol in Road Crashes

Studies carried out in the United States and other developed nations since the 1930s indicate a strong, direct relationship between increasing blood alcohol concentration (BAC) in a motor vehicle driver and increasing risk of his involvement in a road crash.[1,2]

From the Council on Scientific Affairs, Division of Personal and Public Health Policy, American Medical Association, Chicago.

Report A of the Council on Scientific Affairs, adopted by the House of Delegates of the American Medical Association.

This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve.

Reprint requests to Division of Personal and Public Health Policy, Council on Scientific Affairs, American Medical Association, 535 N Dearborn St, Chicago, IL 60610 (John C. Ballin, Phd).

A driver's relative risk of having a road crash shows a dramatic rise as the driver's BAC increases (Figures 1 and 2).[3,4] Alcohol-impaired drivers are believed to be responsible for 25% to 35% of all crashes causing serious injury and 6% of all crashes. In single-vehicle crashes, 55% to 65% of fatally injured drivers have BACs of 0.10% or greater.[3]

In most states of the United States, a BAC of 0.10% is the legal definition of being under the influence of alcohol for driving-under-the-influence (DUI) prosecution. Since 1960 the AMA has recommended that a blood alcohol level of 0.10% be accepted as prima facie evidence of being under the influence, a position that the Council on Scientific Affairs believes should be revised to a lower BAC in light of scientific evidence. Significant alcohol involvement in injury-causing road crashes begins at a driver BAC of 0.05%. In a recent review, Johnston[5] concluded that 10% of drivers in crashes that cause property damage had BACs of 0.05% or greater and that 16% to 38% of drivers in injury-causing crashes had BACs of 0.05% or greater (Table 1).

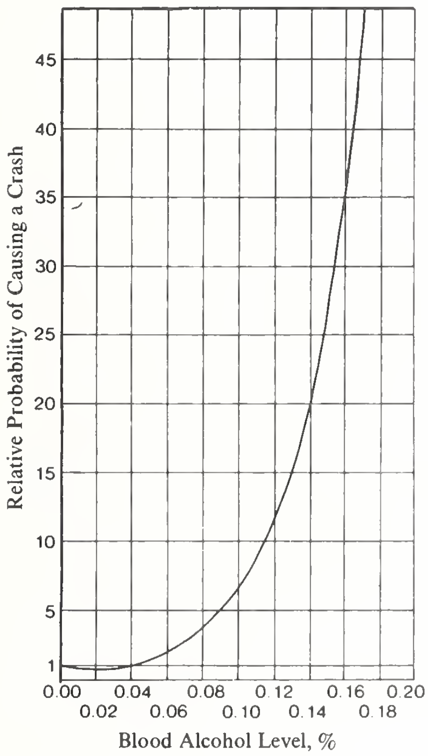


Figure 1
Relative probability of causing crash rises with rising blood alcohol levels.

In 1982, one in three persons killed in Australian road crashes and one in five injured had a BAC of 0.05% or more.[5] McDermott and Strong[6] found that drivers with alcohol levels of 0.05% or more have a greatly increased risk of being involved in a road crash causing injury or death. In the first three years of compulsory BAC testing of adult road crash victims in Australia's Victoria State, 27.1% of 21,863 male driver casualties and 8.7% of 9,187 female driver casualties had BACs exceeding the Victoria legal limit of 0.05%. Soderstrom et al[7] reported that of 413 road crash victims with measurable BACs at an emergency medical services center in Maryland, 91 had BACs of less than 0.10%.

Table 1
INCIDENCE OF BLOOD ALCOHOL CONCENTRATIONS OF 50 mg/dL, BY CRASH SEVERITY AND TYPE OF ROAD USER

	Crash Severity, %		
Type of Road User	*Property Damage*	*Injury*	*Fatal*
Driver	10	16-38	45-55
Passenger*	. . .	25	25-35
Motorcyclist	. . .	22-25	35
Pedestrian*	. . .	19-25	30

*Percentage shown is of those older than 14 years.

Alcohol involvement in crashes had been called an epidemic, with little diminution in its proportions despite heightening of public consciousness by the activities of various community groups and anti-drunk-driving campaigns.[8] Ravages of the epidemic have been greater among the young. Fatal Accident Reporting System (FARS) data show, from 1977 to 1981, a steady increase in the overall proportion of measureable blood alcohol levels in drivers aged 16 to 25 years involved in fatal crashes.[9] The authors believed the data to be more representative of patterns of alcohol use in that age group than improvement in BAC testing and reporting.

Drivers aged 16 to 19 years have the highest rate of alcohol-involved fatal crashes per unit of travel.[8] Epidemiologic data from FARS also indicate over a number of years that younger drivers involved in fatal crashes have lower average BACs than older drivers.[10] Previous reviews of biographical variables in alcohol-related crashes furnished the same finding.

The role of alcohol in crashes of teenage drivers also is indicated in FARS data for 1981 showing that twice as many with positive BACs were involved in single-vehicle crashes as opposed to multiple-vehicle fatal crashes. A driver in a single-vehicle accident is presumed responsible for his own crash. In the same data, five times more male than female teenage drivers were involved in single-vehicle fatal accidents, bearing out by trend if not by precise ratio another consistent biographical finding.[9]

Analysis of 1983 FARS data showed that 33% (17,764) of all drivers in fatal road crashes that year were 16 to 24 years old. Of that number, 38% (6,833) were alcohol involved, compared with 26% in all other age groups. Fatalities in road crashes involving drinking drivers aged 16 to 24 years numbered 7,784 in 1983, of whom 51% (3,992) were the drivers themselves.[11]

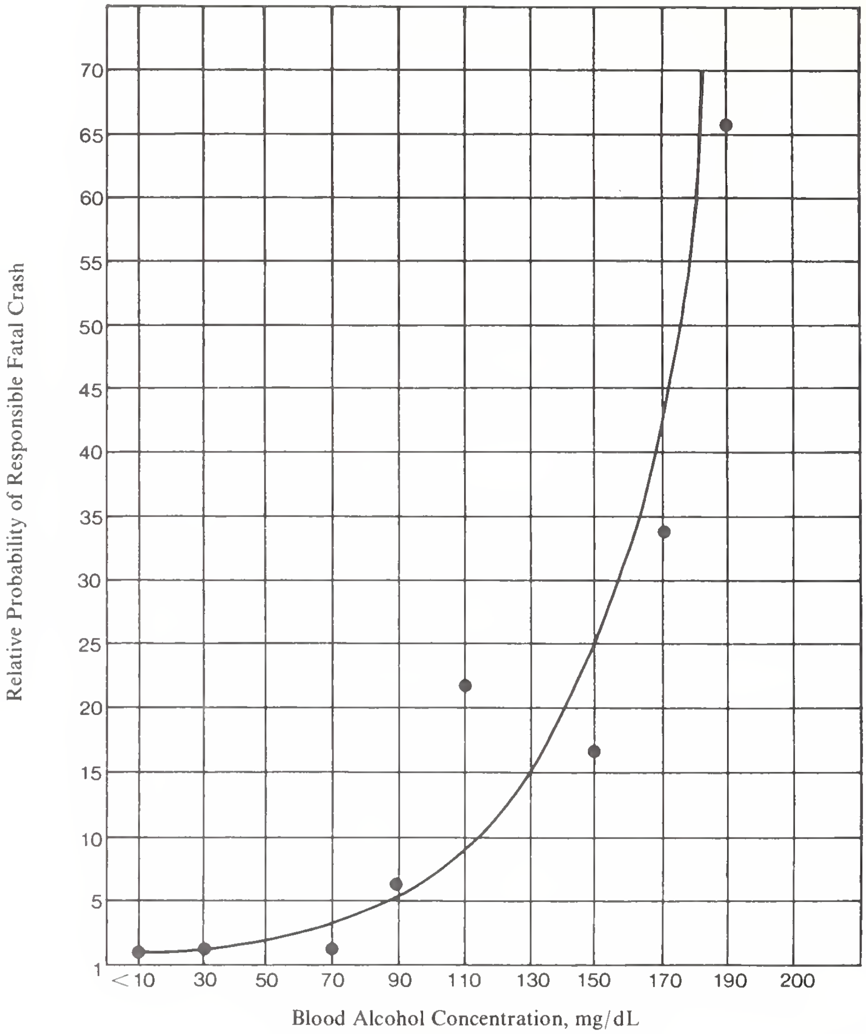


Figure 2
Relative probability of being responsible for fatal crash rises with rising blood alcohol concentrations.

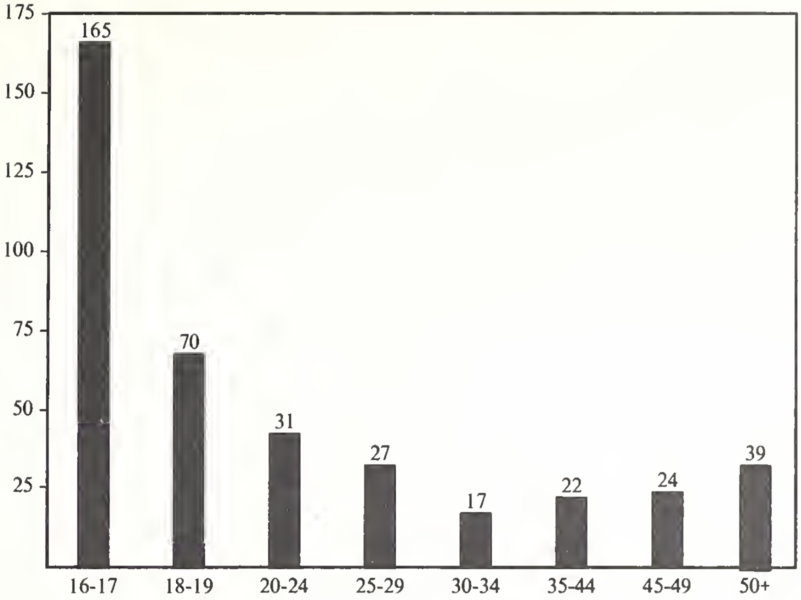
A model developed by Simpson[12] (Figure 3) shows the relative risk by age group of having a fatal crash if drivers were impaired by BACs of 0.08% or greater. With the risk of a sober driver having a fatal crash set at 1, the risk for impaired 16- to 17-year-olds is 165.

Young drivers are overrepresented in crashes and also in alcohol-involved crashes when BACs are low to moderate. Overrepresentation may include exposure (miles driven) as a component. Overrepresentation at low BACs may be a function of younger drinkers having less alcohol tolerance than experienced drinkers and younger drivers having less experience than older drivers.[10]

The Effects of Alcohol

One effect of alcohol in road crashes is its contribution to enhancement of injury in alcohol-impaired victims. Prevention or limitation of trauma is less likely in alcohol-impaired drivers because they are less likely to use seat belts.[13,14] Contrary to the popular belief in being "too drunk to get hurt," more alcohol-impaired crash victims suffer serious injury than sober victims.[15] Alcohol complicates the physician's task of treating trauma: neurologic injury may be masked by drunkenness, and acute and/or chronic intoxication may be linked to a considerable range of metabolic disturbances, as well as to altered responses to anesthesia and alterations in host defenses against infection.[7] Experimentally controlled injuries to laboratory animals result in lower survival rates for animals first given alcohol and more extensive intracranial hemorrhage in alcohol-impaired animals after experimental penetration of brain tissue.[16,17]

The influence of alcohol related to driving behavior and driving skills is mediated through its effects on the central nervous system, similar to those of general anesthetic. Alcohol in small doses may cause performance of driving-related skills to fall off; in moderate to high amounts, alcohol diminishes performance across the board with general impairment of nervous function. Effects may vary with psychological profiles, tolerance to alcohol, and experience with the drug.



Total Impairment Risk Factors
Figure 3
Age group and risk of fatal collision if impaired.

Dose/weight charts may not be appropriate guides to drinking behavior.[18] Biologic variability of response to alcohol has been demonstrated under controlled experimental conditions with both male and female subjects: in single-dose drinking tests the elapsed time from end of drinking to peak BAC varied from 14 to 138 minutes in one group, and in a followup study the same investigator found a 14-fold variation between absorption times in different subjects.[19,20] Women achieve higher peak BACs than men when given identical weight-adjusted doses.

A review of seven studies spanning a 50-year period (Table 2) indicates that at BACs of up to 0.05%, 0% to 10% of persons were considered to be "drunk"; at levels of 0.05% to 0.10%, 14% to 68% of persons were considered to be "drunk"; and at levels of 0.10% to 0.15%, 83% to 97% were considered to be drunk.[21]

The deleterious effect of alcohol at BAC levels of 0.05% to 0.06% is seen in persons performing curve-negotiating "driving" tasks under laboratory conditions. Verhaegen et al[22] concluded that at BACs between 0.05% and 0.06%, performance in information processing and curve-negotiation skill deteriorated in test subjects. Burns and Moskowitz[23] observed a 10% to 15% degree of impairment at BACs of 0.05% to 0.08% when subjects had to perform a divided-

Table 2
RELATION BETWEEN BLOOD ALCOHOL LEVEL AND DRUNKENNESS

% of Persons Found to Be Drunk										
*0.00-0.05**	*0.051-0.10*	*0.101-0.15*	*0.151-0.20*	*0.201-0.25*	*0.251-0.30*	*0.301-0.35*	*0.351-0.40*	*0.401*	*Total Persons Examined*	*Investigators†*
0	19	50	83	93	98	100	100	. . .	1,984	Widmark 221
2	38	93	97	99	100	100	. . .	. . .	950	Schwarz 195
10	18	47	83	90	95	96	93	100	1,000	Jetter 133
10	68	81	92	97	100	. . .	. . .	. . .	1,712	Andersen 9
0	46	50	92	100	100	100	100	100	140	Harger 111
0	14	69	90	94	94	100	100	100	100	Prag 186
7	25	49	85	93	97	98	100	99	750	Hine 123
4	32	62	89	95	98	99	99	100	6,594	. . .

*Percent weight by volume (0.05% w/v=150 mg/dL; 0.15% w/v=150 mg/dL) of blood alcohol.
†Numbers under names of investigators are reference citations in reference 35, source of Table 2.

attention task of tracking and reaction. Attwood et al[24] tested drivers on closed-course conditions and using a multivariate analysis technique found that drivers with BACs of 0.06% to 0.08% exhibited more variability than alcohol-free drivers in lane position, brake use, and steering controls. Impairment of judgment by alcohol was demonstrated at BACs as low as 0.04% when skilled bus drivers misjudged their ability to drive a vehicle through a space as much as 12 in narrower than the bus.[25]

Johnston[5] states that many tests of alcohol use and skills relevant to driving show that both information acquisition and information processing are rendered slower and less efficient, and the ability to carry out a divided-attention task that requires intellectual time sharing is impaired. He hypothesizes that when impaired drivers enter curves, they devote so much attention to the steering task that other perception of cues related to road curvature suffers, and they fail to reduce speed adequately.

Chemical Tests for BAC

Determination of BAC is made directly by chemical testing of blood drawn from the subject or indirectly by testing of expired breath or urine. More and more, breath-alcohol analysis is performed for the purpose of determining the concentration of alcohol in breath, rather than for attempted conversion to blood-alcohol concentration. Other fluids and tissues may be tested but usually are not in the living subject; recently, there has been a revival of interest in saliva-alcohol testing.

Laboratory methods for analysis of blood samples include (1) chemical reduction of acid dichromate, (2) enzymatic oxidation by alcohol dehydrogenase with colorimetric determination of NADH (the reduced form of nicotinamide - adenine - dinucleotide) conversion, and (3) gas-liquid chromatography. Choice of the method used by a laboratory may be influenced by the size and sophistication of the facility and the reliability of the method for confirmation of roadside breath analyses. All three methods have strengths and weaknesses, but gas chromatography is the most accurate and best suited for handling large numbers of samples. It also has the advantage of sensitivity to other aliphatic alcohols or volatile toxins that a suspect may have been ingesting with, or without, ethanol.[26]

Breath analysis is by far the most common method of measuring BAC. The concentration of ethanol in one volume of blood is stated in most textbooks and highway safety regulations to be equivalent to that in 2,100 volumes of alveolar air.[27]

Dubowski[28] challenges the 2,100:1 conversion factor on the basis of sophisticated chemical analyses of blood and breath alcohol. He and O'Neill place the mean alcohol partition factor between blood and breath, in the postabsorptive phase in healthy adult males, at approximately 2,300:1, with a range of 1,797:1 to 2,763:1 for 95% of a population of 393 healthy adult men and a range of 1,555:1 to 3,005:1 for 99.7%. Quantitative breath-alcohol analyzers are all currently factory calibrated to a conversion factor of 2,100:1 to meet official guidelines of the National Highway Traffic Safety Administration. Dubowski questions whether the conversion of breath alcohol concentration to BAC should be retained for forensic purposes and recommends that breath alcohol concentration alone be used for statutory definition of DUI.

That the 2,100:1 ratio is too low has been raised as a possibility to explain why breath analysis values from one well-regarded instrument are on the average 10% to 15% lower than alcohol concentration in blood samples taken at the same time.[29]

In a seven-month trial in London of three types of breath-testing instruments used in the United States, the breath-testing instruments tended to underread actual blood alcohol levels by 0 to 20 mg/dL in the BAC range of 0.05% to 0.10%.[30]

The US National Highway Traffic Safety Administration publishes model specifications for the performance, calibration, and testing of breath alcohol testing devices to ensure their reliability.

DUI Countermeasures

Strengthening of state DUI laws has been a trend over the past several years.

State legislators are apparently recognizing that a growing national consensus against driving under the influence must be backed by specific laws needed by police, courts, and licensing agencies to get alcohol-impaired drivers off the road.

The AMA in May 1982 issued to state and medical specialty societies a document titled "Drunk Driving Laws" and urged state medical associations to consider seeking enactment of legislation to strengthen DUI laws in their respective states.

The AMA House of Delegates at its 1983 Annual Meeting (Resolution 95, A-83) reaffirmed AMA policy to encourage each state medical society to seek and support legislation to raise the minimum drinking age to 21 years, and it urged all physicians to educate their patients about the dangers of alcohol abuse in general and operating a motor vehicle while under the influence of alcohol in particular.

Among the more visible and easily identified strenthening of state DUI laws is the replacement of "presumptive" by "per se" laws. The latter laws make it illegal in and of itself to drive with a BAC over certain specified limits. In states with "illegal per se" laws, proof of driving under the influence of alcohol is automatic when a properly administered test of the specified type shows the driver's BAC to be over a specified limit. Most states with illegal per se laws set the BAC limit at

0.10%, but the range among all such state laws is from 0.08% to 0.15%.

A variation on the illegal per se law is a two-step law adopted in some states: (1) illegal per se at a specified BAC, and (2) presumption of driving under the influence set at a lower BAC, requiring supporting evidence other than breath or blood test for prosecution.

The Highway Users Federation recommends an illegal per se law as one provision in any driving legislative package. Provisions include (1) administrative driver's license suspension, whereby the license of any driver arrested for driving under the influence is suspended for a specified period, with harsh penalties imposed for driving while the license is suspended (the measure is aimed at the repeat offender); and (2) recording of all alcohol-related arrests, a provision meant to identify repeat offenders and particularly those whose alcohol-related arrests are frequently plea bargained to a lesser charge not related to alcohol.

In reviewing the recent records of control measures, Waller[31] identified two as being associated with positive results: (1) An increase in the age at which one can be issued a driver's license or can drink legally seems to have a positive effect in reducing the number of alcohol-related crashes by 16- and 17-year-olds. (2) License suspension or revocation is the most cost-effective countermeasure yet identified for reducing driving by drunk driving offenders. Arrest, trial, and imprisonment are far more expensive in public servant time and public funds. Revocation of a license for driving under the influence may be mandatory on conviction or may occur administratively upon evidence that the person committed the offense. Waller noted that several investigators have reported that one third to two thirds of persons with revoked licenses continued to drive while the revocation or suspension was in effect but were driving less often and more carefully; multiple DUI offenders who were suspended had better subsequent records than comparable convictees whose licenses were not suspended.

The impact of per se legislation upon deterrence of alcohol-impaired driving was unclear in four reviews of the data, according to Waller. A difficulty often encountered was the inability of the reviewer to separate the effect of per se laws from that of other countermeasures instituted at about the same time in the same states.[31]

Comparison of mandatory licensing sanctions with education and rehabilitation programs for DUI offenders in four states demonstrated clear superiority of the licensing sanctions in reducing DUI recidivism and subsequent crash involvement.[32]

Research and Human-Related Risk Factors

Multidisciplinary investigations of driving and drinking are rare to non-existent. Multiple foci of research interest—eg, highway and auto safety, pharmacology, alcohol and substance abuse, trauma treatment, legislation, and regulation—have tended to operate without strong linkages.

On three occasions, in 1972, 1978, and 1983, large assemblies of North American investigators ranked human-related risk factors at or near the top of DUI research needs. In each instance, the group asked for multivariate studies that incorporate human-related variables of an attitudinal-personality nature and a long-term research strategy coordinated through some central organization.[33]

Youthful driving and drinking is an area where research on multicasuality seemed urgently warranted to investigators, in light of the peculiarly high risk of death and injury from alcohol-related crashes in this group.[34] Some suggestive research indicates that drinking and driving populations contain drinking/driving/crash-prone subpopulations in whom the influence of alcohol on emotions and attitudes may be an important causative factor.[35] The influence of alcohol on an emotionally charged driving style may be as important as its influence on driving skill.[30]

Social and cultural factors that influence the magnitude, characteristics, and persistence of the drinking and driving problem are not yet defined. Whether sustained shifts in social norms related to drinking and driving can be brought about—as they were in relation to littering, smoking, and diet/fitness/heart disease—is a question yet to be answered.[36]

Conclusions

1. Alcohol causes deterioration of driving skills beginning at 0.05% BAC (50 mg of ethanol per deciliter of blood) or even lower. Deterioration progresses rapidly with rising BAC to serious impairment of driving skills at BACs of 0.10% and above, according to scientific consensus.

2. Drivers with BACs of 0.05% to 0.10% are significantly represented in road crash statistics.

3. Drivers aged 16 to 21 years have the highest rate of alcohol-involved fatal crashes per mile, with lower average BACs than older drivers.

The Council on Scientific Affairs recommends that the AMA (1) direct public information and education against *any* drinking by drivers and encourage other organizations to do the same; (2) adopt a position supporting a 0.05% BAC as per se illegal for driving and urge incorporation of that position into all state DUI laws; (3) reaffirm the position supporting 21 years as the legal drinking age, strong penalties for providing alcohol to persons younger than 21 years, and stronger penalties for providing alcohol to drivers younger than 21 years; (4) urge adoption by all states of an administrative suspension or revocation of driver licenses after DUI conviction and mandatory revocation after a specified number of repeat offenses; (5) encourage automobile industry efforts to develop a safety module that thwarts operation of a car by an intoxicated person.

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The President's Page

The Doctor-Patient Relationship: What Does the Future Hold?

Treating the individual patient under the new modes of health care financing and delivery presents many interesting possibilities. This is especially true since, over the years, a very distinct and powerful physician/patient relationship has developed, which has placed health care delivery on a very personal, individual basis. Major medical decisions are based on individual patient needs and financial structures have been developed to cover these needs. With the development of newer skills, knowledge. and resources we have been able to intervene in a wider range of diseases. Our patients have been the ones to benefit from this.

We are now faced with a whole new range of issues that have never surfaced before. The flouridation of water, for example, has now been superseded by questions of gene therapy and organ transplants. Cost containment has come to the forefront and with it, the fundamental conflict between the welfare of the individual and the welfare of the community.

While our goal has always been to serve the individual patient, and although no one is directly challenging this notion, a series of events mostly involving cost portend a shift toward community good and away from individual good.

The advent of prospective payment systems and diagnosis related groups shift the emphasis from the individual patient to the patient as a member of a group or class. With this system, if you do not fit the pattern, you may fall through the cracks. It is creating a disruption in the traditionally individual health oriented system and replacing it with a group oriented system.

All of these systems have as their basis, cost effectiveness. This in turn requires the allocation of certain health care resources because the plan will only pay for certain things. Thus, instead of concentrating on the benefit of the individual the new approach focuses on the cost to a group. When and if this philosophy is applied to patient care, one has to wonder who will decide the fate of those patients who do not fit the pattern. Inherent in this system is also the question of how much autonomy the physician will retain over the physician/patient relationship and medical decision making. Will the responsibility for these decisions be shifted away from the physician to attorneys, committees or other non-physician providers? In other words, the interests of the individual patient may be sacrificed for the greater good of society. While we have not reached this point, and hopefully never will, one can picture a scenario where patient care will be based on whether the patient is *worth* treating. "Worth", being a group or community decision. We have to wonder if this is what the future will hold with the advent of the corporate practice of medicine.

As physicians, we must remain diligent in our role of patient advocate and strive to maintain our orientation toward our patient and quality care.

Joseph C. Czarsty, M.D.
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Reflections on Medicine

Trade or Profession?

ROBERT U. MASSEY, M.D.

The members of the medical school class of 1990 already know who they are; all summer they have been looking forward to beginning work in their chosen profession. They are the practitioners and physician scientists who will be hitting their stride in the first decade or two of the new century, and will be thinking of retirement around the year 2029 when some of their sons and daughters will be reaching the peak of their professional lives in medicine.

None of us can see that far; beyond five or ten years "we see through a glass darkly," but as teachers our task is to prepare this class of '90 for work in the early years of the second millenium. The science and skills are straight forward enough; the students are bright and eager to learn, and the faculty, for the most part, eager to teach. Sometime during this first year we must begin to help these young men and women to define for themselves the science, the art, and the practice of medicine.

When we ask about differences between a trade and a profession, we may have to face some embarrassing examples. Comments about exceptions proving rules may sound unconvincing when we try to explain the doctors' strike called by the Ontario Medical Association last June; it helps but little to be assured that the strike was not over money but rather over professional freedom. Whatever the merits, the words "striking profession" may sound to some of our students, and, I hope, to some of us, like an oxymoron. Anyway doctors here don't strike.

Since most of our students are Connecticut residents they will have read about the striking nurses and other "health workers" at Waterbury Hospital; does profession mean one thing to doctors, another to nurses? A strike which puts patient care at risk can hardly be reconciled with the principle of putting the patients' interests ahead of all others, or in the words of the Oath, to "abstain from whatever is deleterious and mischievous."

But striking, withholding care, is an extreme action, taken out of desperation; perhaps some doctors and nurses can rationalize trade union tactics by appealing to a higher good: professional freedom or improved patient care. Students are idealistic about medicine, but as realistic as the rest of us about our poor imperfect humanity; they are not likely to ascribe higher motives than necessary to explain behavior.

If indeed our students are not students at all, only trainees preparing themselves for employment as technicians in the corporate health care industry, then our task of definition becomes simpler: medicine is a trade, patients are consumers, government and industry are purchasers, and the words *profession* and *vocation*, if they carry any meaning, signify an idea out of fashion.

Even a little acquaintance with the history of medicine will remind us that we've been through all this before; that raising these matters now suggests that we are working on a better definition of medicine and of our professional work.

Recently the physician and philosopher Leon Kass has written: "Outside the profession, there are various efforts to cut medicine down to size: not only widespread malpractice litigation and massive government regulation, but also various attempts by consumer groups and others, to redefine medicine as a *trade* rather than a *profession* and the physician as a morally neutered technician for hire under contract."[1] But Kass is an optimist and believes that we shall be compelled to reassert "the meaning of professing medically."

"For if healing the sick is always the heart of the physician's business, and if, as I suspect, the *essential* features of the healing relationship between the physician and the ill have not been, indeed cannot be, altered by technological advance or social change, then medicine must remain, *at its core*, what it always has been: a very special profession, with its own goals, means, and intrinsic norms of conduct."[2]

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The United States Supreme Court 1986: Continuity and Transition

JOSEPH M. HEALEY, J.D.

The closing weeks of a Supreme Court term are frequently periods of great activity when noteworthy cases are decided and shifts in court personnel occur. This past June was no exception, as three cases with medicolegal significance were decided and the Chief Justice announced his resignation. These events reflect both the influence of continuity and transition upon the Court and underscore the increasingly important role which the Court has come to play in health law.

To no one's surprise, abortion was once again before the Court. At issue in this year's case[1] were provisions of a Pennsylvania statute that mandated a series of disclosures by the physician to the woman contemplating an abortion and by the physician to the state. Among the disclosures to the woman were: facts about the abortion procedure; information about the availability of support to help the woman carry her child to term and to assist her after the child is born; and descriptive material about the probable anatomical and physiological characteristics of an unborn child at two-week gestational increments. Among the reporting requirements imposed upon the physician were descriptive information about the woman seeking abortion, the basis for determining that the fetus was non-viable or that an emergency justified the abortion. A very divided Court held 5-4 that these provisions of the Pennsylvania statute were unconstitutional. The essence of the majority position was expressed by Justice Blackman who wrote:

> "The States are not free, under the guise of protecting maternal health or potential life, to intimidate women into continuing pregnancies. Appellants claim that the statutory provisions before us today further legitimate compelling interests of the Commonwealth. Close analysis of those provisions, however, shows that they wholly subordinate constitutional privacy interests and concerns with maternal health in an effort to deter a woman from making a decision that, with her physician, is hers to make."[2]

In contrast, Justice White in his dissent argued that it is time to recognize that *Roe v. Wade* was improperly decided and should be overriden. His language reminds us of the deep divisions which remain about abortion:

> "The decision today appears symptomatic of the Court's own insecurity over its handiwork in *Roe v. Wade* and the cases following that decision. Aware that in *Roe* it essentially created something out of nothing and that there are many in this country who hold that decision to be basically illegitimate, the Court responds defensively. Perceiving, in a statute implementing the State's legitimate policy of preferring childbirth to abortion, a threat to criticism of the decision in *Roe v. Wade*, the majority indiscriminately strikes down statutory provisions that in no way contravene the right recognized in *Roe*. I do not share the warped point of view of the majority, nor can I follow the tortuous path the majority treads in proceeding to strike down the statute before us. I dissent."[3]

The impact of the resignation of Chief Justice Burger, the nomination of Justice Rehnquist as Chief Justice and the nomination of Judge Antonin Scalia to fill the Associate Justice seat vacated by Justice Rehnquist, upon the abortion issue is unclear. Both nominations must first be confirmed by the Senate. The resignation of Justice Burger does not, in itself, shift the balance in the 5-4 majority. In my last two columns I described the change in emphasis by abortion supporters seeking to establish more extensive rights to abortion under state constitutions. Opponents of abortion will try in two states this fall to amend their state constitutions to limit access to abortion. The debate will continue, and there is no clear resolution in sight for this bitter area of societal disagreement.

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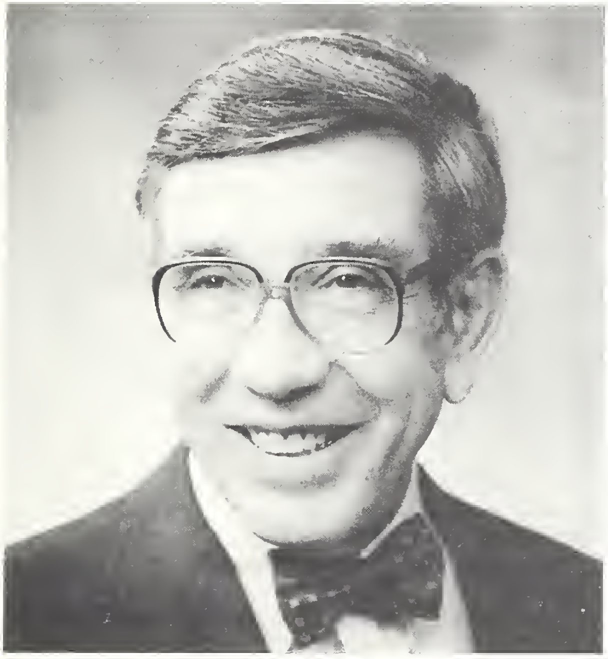
Editorial

Dr. Robert U. Massey Appointed Editor of *Connecticut Medicine*



Robert U. Massey, M.D.

A short time ago, I wrote here that news would shortly be forthcoming regarding the appointment of the permanent Editor for *Connecticut Medicine.* The work of the Search Committee has come to fruition with the welcome news that Dr. Robert U. Massey, former Dean of the University of Connecticut School of Medicine, has accepted this position. The appointment was made by the Council of the Society at its June meeting and was received very enthusiastically by the Council and also by many other people that I have spoken with recently. In Dr. Massey, I feel that the Search Committee has found an extraordinary combination of scholarly pursuits, an involved interest in "town and gown" affairs, and the most comprehensive and exact knowledge of the needs of organized medicine and private practitioners. Dr. Massey has a curriculum vitae which occupies many pages. Also of importance to us, I feel, is the fact that his monthly contribution in *Connecticut Medicine,* formerly "Reflections from the Dean's Office" and now known as "Reflections on Medicine," has always received the widest readership and recognition from our readers over many years.

Dr. Massey was educated at Oberlin College and the University of Michigan. He graduated from Wayne State University College of Medicine in 1946. He spent many years in Detroit, Michigan and in Albuquerque, New Mexico in educational positions until coming to us at the University of Connecticut School of Medicine in 1968. He was Dean from 1971 to 1985. He is a diplomate of the American Board of Internal Medicine and has shown a special interest in the field of medical education. His other interests lie in the history of medicine. His interest in medical writing is well demonstrated by a large body of publications. I am sure that we all share in the confidence that Dr. Massey will continue to make *Connecticut Medicine* a journal which will be read with enthusiasm.

I can speak on behalf of the Search Committee to thank all who expressed interest in the Editorship of *Connecticut Medicine.* It has indeed been a pleasure to work with this Search Committee and also as Editor Pro tem of *Connecticut Medicine.* I will most assuredly help our new Editor in any way that I can and will continue serving on his Editorial Board as long as requested.

Dr. Massey has already been active in the transition period of our *Journal.* As you may know, material for the issues are worked on two to three months ahead of time for planning purposes. We are all quite enthusiastic about the forthcoming September issue, which will be our special 50th anniversary issue of *Connecticut Medicine.* In view of my suggestions and excitement over this issue, Dr. Massey felt that it was proper to leave my name on the masthead, as Editor Pro tem, until this issue. We are all equally enthusiastic to proceed with *Connecticut Medicine* under the guidance of Dr. Massey.

Stewart J. Petrie, M.D.
Editor Pro tem

WILLIAM R. RICHARDS, M.D.
1908 - 1986

Dr. William R. Richards died at his home on June 24. Dr. Richards was born in Boston, January 20, 1908 and was a resident of Hamden for 40 years.

He received his A.B. degree from Cornell University in 1931 and his medical degree from the Cornell University Medical College in 1935. After two years of internship at Bellevue Hospital, New York City, he served at Princeton University as a student health physician before returning to Bellevue where he completed his residency training in obstetrics and gynecology.

Dr. Richards served 38 months during World War II as a general duty officer and chief of obstetrics and gynecology. He was discharged from the U. S. Medical Corp of the Air Forces with the rank of major in 1946.

Following his military service, Dr. Richards entered private practice in New Haven, where he practiced obstetrics and gynecology and served on the staffs of both the former Grace-New Haven Community Hospital, now Yale-New Haven Hospital, and the Hospital of St. Raphael. At St. Raphael's he was senior attending physician in his specialty, and was active on various staff committees. He contributed several articles to the *Journal of Obstetrics* and *Gynecology* and was a diplomate of the American Board of Obstetrics and Gynecology. He also served as President of the New Haven Obstetrical Society.

In 1958, during a period of unrest in the private practice of medicine, Dr. Richards became known among his colleagues as a staunch supporter of physicians practicing medicine independently, without the interference of governmental and other outside agencies. CSMS leaders elected him Secretary of the Connecticut State Medical Society. Within a few months, he was asked to accept the post of full time Executive Director, which had been vacated. The decision to leave active practice was a difficult one, and finally he decided to accept the post, which he held until his retirement in 1977.

During his tenure as Executive Director, Dr. Richards served on the National Committee to Selective Service, many committees of the Connecticut State Medical Society, including the Committees on State and National Legislation, Committee on Public Health, Advisory Committee on School Health, Conference Committee with the Connecticut Bar Association, Conference Committee with the Connecticut Pharmaceutical Association, Advisory Committee on Medicare Plan, and was a member of the Conference of State Health Organizations and the Connecticut Health League.

Dr. Richards filled his post with distinction and dedication and gave two decades of outstanding service to the Connecticut State Medical Society and its members. His wise counseling contributed greatly to the credit of medicine in Connecticut.

The remarks which he made after being honored at his last House of Delegates meeting as Executive Director exemplify his beliefs. . . . "that in the overall picture of medical care, we cannot forget the fact that it is the patient who ought to come first and that in the affairs of medicine, which are strictly of a professional nature, I think the Society should always realize that it does not own its members, they are members by their own volition and, therefore, CSMS should always act in the best representative capacity it can to promote their interest, not beyond reasonable levels, but certainly not to sit back and let the government take over, if there is any way in God's world that it can be prevented."

Dr. Richards was married to Friederike Hafekost and leaves three sons, William F. Richards of West Suffield, Douglas E. Richards of Budd Lake, New Jersey, and James G. Richards of Hamden and nine grandchildren.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, CT 06511 Telephone 865-0587

Timothy B. Norbeck, *Executive Director*

Josephine P. Lindquist, *Associate Executive Director*

Raymond T. Sullivan, Jr.
Assistant Executive Director
Public Affairs

Robert J. Brunell
Assistant Executive Director
Scientific Activities

Shelley A. Marcus
Director of
Government Relations

Council Meeting
Thursday, June 5, 1986

Organizational Meeting

The organizational meeting of the Council for 1986-87 was called to order by the President, Joseph C. Czarsty, M.D. Following some opening remarks and the introduction of Council members, elections of a Chairman and Vice-Chairman of the Council for 1986-87 were held. Those elected were: Chairman, Guy W. Van Syckle, M.D., Danbury; Vice-Chairman, Mehdi S. Eslami, M.D., Waterbury.

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle were: Drs. Ahamed, Ahrens, Beck, Bobruff, Bonner, Czarsty, Dardick, Finn, Fox, Freedman, Friedberg, James, Kamens, McDonnell, Orphanos, Petrie, Ragusa, Reyelt, Robbins, Sullivan, Sweet, Villa, Waldron, Welch, Wetstone, Zlotsky.

Also present: Dr. Whalen, Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Sullivan, Mr. Staples, Ms. Marcus, Mr. Tomat, Mr. Freberg, Mr. Coffey, and Mrs. Ganguli (President Auxiliary).

Absent were: Drs. Abbot, Canzonetti, Eslami, Rose, Schwartz, Zanker.

Report of the President

a. *Leadership Conference:* Dr. Czarsty reported that arrangements for the 1986 Leadership Conference were underway and that it is scheduled to be held at the Sheraton Waterbury Hotel on September 6. Following discussion, it was VOTED that invitations should be extended to all members of the House of Delegates and alternates, county officers, CSMS section officers, chiefs of staff of Connecticut hospitals. It was also VOTED to establish a $20.00 registration fee to partially offset the cost of the conference.

b. *County Presidents' Conference:* Dr. Czarsty reported that it was his intention to follow Dr. Whalen's practice of holding periodic meetings with county presidents in order to facilitate communications between the county associations and the State Society. He also planned to initiate conferences with section presidents for the same purpose.

Report of the Executive Director

Mr. Norbeck reported on several items:

a. *New Executive—New Haven County Medical Association:* Mr. Norbeck formally introduced Gary Freberg and noted that he had replaced Mark Meister as Executive Director of the New Haven County Medical Association.

b. *IPA/HMO:* He reported that the CSMS staff was spending a great deal of time on the IPA/HMO project and that it was progressing on schedule.

c. *Tort Reform:* It was noted that despite Ralph Nader's entrance into the tort reform dispute, Governor O'Neill was expected to sign the measure soon.

d. *Courtesy Card:* The Medicare courtesy card program is underway and meetings have already been held with several of the county associations and it is hoped that a statewide program can be implemented by fall.

e. *Hospital-Medical Staff Section:* The minutes of the organizational meeting of the Hopital-Medical Staff Section have been distributed to members of the Council for their information. Dr. Edward Dunn was elected Chairman and the next meeting was tentatively scheduled for June 24, 1986.

Editor of Connecticut Medicine: Dr. Van Syckle, Chairman of the Council reported on the progress made in a search for an Editor for *Connecticut Medicine.* He stated that Dr. Sherwin Nuland, who had been offered the editorship, declined because the conditions of employment were not acceptable to him. Dr. Van Syckle reported that he asked Dr. Robert Massey to accept this appointment and was pleased to report that Dr. Massey would accept the post of Editor of *Connecticut Medicine.* The Council accepted this report with applause and VOTED to appoint Dr. Robert Massey Editor of *Connecticut Medicine.* It is expected that Dr. Massey will assume the post in early fall.

It was further VOTED to express sincere appreciation of the Council to Dr. Stewart Petrie and commend him for the outstanding job he did as Editor Pro tem and applauded him for his guidance of the *Journal* during the interim period.

CSMS IPA-HPA Steering Committee

In keeping with the action taken by the House of Delegates that a steering committee be elected by the Council, after consultation and nomination from the county associations, it was VOTED to approve the following actions:

a. That the steering committee would be made up of two voting delegates and one alternate from each county association.

b. That the President, President-Elect and Chairman of the Council be members of the steering committee with a vote.

c. That Dr. William A. Whalen, Jr., Willimantic, serve as Chairman and Dr. James Orphanos, Greenwich, serve as Vice-Chairman of the steering committee.

d. That the Chairman of the steering committee be given the right to invite any consultants he wishes who would be beneficial to the Society and its activities.

Following review of the county nominees for the CSMS IPA/HMO Steering Committee, the following names submitted by the counties were approved:

Fairfield: Patrick J. Carolan, M.D., Bridgeport (D) — Orthopedic Surgery; Seyed H. Aleali, M.D., Bridgeport (D) — Internal Med. Oncology; Lawrence M. Blum, M.D., Fairfield (A) — Dermatology.

Hartford: Kenneth Johnson, M.D., New Britain (D) — Surgery; Robert Rodner, M.D., Manchester (D) — Urology; Annemarie Welch, M.D., New Britain (A) — Internal Medicine.

Litchfield: William A. Handleman, M.D., Torrington (D) — Internal Medicine & Nephrology; Evan P. Provisor, M.D., Sharon (D) — General & Vascular Surgery; George Rubin, M.D., Torrington (A) — Orthopedic Surgery.

Middlesex: Kenneth Robbins, M.D., Middletown — Pediatrics; Vincent Catrini, M.D., Middletown — Surgery; James E. Brown, M.D., Middletown — Internal Medicine.

New Haven: George A. Bonner, M.D., New Haven (D) — OB/GYN; Morton H. Silberstein, M.D., New Haven (D) — Psychiatrist; Marvin I. Fox, M.D., Milford (A) — Internal Medicine & Gastroenterology.

New London: David D. Thompson, M.D., Niantic — Internal Medicine; Mahmood Okasha, M.D., Norwich — Psychiatry; Lorry Coletti, M.D., Norwich — General & Vascular Surgery.

Tolland: Francis Van Nostrand, M.D., Stafford Springs (D) — Internal Medicine; Norman Zlotsky, M.D., Rockville (D) — Orthopedics; Alfredo A. Arbulu, M.D., Enfield (A) — General Surgery.

Windham: William A. Whalen, M.D., Willimantic — Surgery; Steven Leach, M.D., Willimantic — Internal Medicine; Stephen M. Upham, M.D., Danielson — Family Practice.

A prolonged discussion was entered into concerning the progress of this undertaking to date. Dr. Whalen and Mr. Brunell reported on the activities of the committee and the hospitals that had already been visited. The Council also listened to a tape by Neil Chayet, business commentator for CBS radio network, which emphasized the importance of physicians organizing themselves.

Medical-Legal Principles of Cooperation

Dr. Stewart J. Petrie discussed the subject of medical-legal principles which were being formulated by a CSMS Ad Hoc Committee and reported that the New Haven County Medical Association had already prepared such a document which had been discussed with the CSMS attorney. Dr. Petrie proposed, and it was VOTED, that Dr. Shelton, Chairman of the CSMS Ad Hoc Committee, be empowered to receive the document prepared by New Haven County along with the attorney's comments and that he re-activate his committee to proceed with this project and to report back to the Council by October 1.

Dates of Semi-Annual and Annual Meeting of the House of Delegates

It was VOTED to approve the following dates:

Semi-Annual Meeting, Wednesday, November 19, 1986
Annual Meeting, Wednesday, May 6, 1987
Scientific Program, Thursday, May 7, 1987

Life Members

It was VOTED to receive for information the following names of Life Members:

Name	Town	Effective Date
Raymond A. Caldarelli	Hartford	1/1/86
Joseph V. DeLuca	Bridgeport	1/1/86
Steven A. Hulme	Hartford	1/1/86
Rudolph E. Klare	S. Woodstock	1/1/86
Hilliard Spitz	New London	1/1/86

Health Policy Agenda Meeting

Dr. Stewart Petrie commented on his report on the HPA meeting held in Chicago on May 15. This is the last meeting of this group. The reports of the work of this group has and will appear in JAMA. Dr. Petrie reported that the aim of the entire HPA is aimed at being an unbiased source of information regarding the best thoughts possible for health care in our country over the ensuing decades. It was VOTED to receive this report as information.

Seat Belt Report

Dr. Kenneth Dardick, who is affiliated with the Seat Belt Coalition, thanked the members of the Council and all physicians for their support of the seat belt law. He reported that in Connecticut there is 80% compliance on major highways and 70% compliance on local roads.

AMA Meeting

Dr. James Orphanos reported that one of the issues at the forthcoming AMA House of Delegates meeting was the funding problem of AMACO (the AMA Reinsurance Company), and whether AMA should seek outside capitalization. He asked if the Council wanted to advise the CSMS AMA delegation on the matter. It was VOTED that there should be no partners in the AMA Reinsurance Company, and that the company should be fiscally responsible and that high enough fees be charged so that the company would be self-supporting.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on March 26, 1986. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

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The Connecticut State Medical Society

The 1986 CSMS House of Delegates

The CSMS House is the supreme governing body of the Society. It meets twice yearly, and is composed of the Society's Council, and the Delegates, elected from their own component county medical association in numbers proportioned to the county's CSMS membership. The following is a list of all 191 current delegates to the House. 151 of them attended the 1986 Annual Meeting which voted to implement the CSMS Statewide IPA-HMO.

FAIRFIELD COUNTY DELEGATES (44)

Seyed Aleali, Bridgeport	Internal Medicine
Lionel G. Brown, Danbury	Surgery
Carmine T. Calabrese, Bridgeport	Plastic Surgery
Robert T. Cassell, Norwalk	Internal Medicine
Eugene H. Corley, Bridgeport	OB/GYN
Robert D. Cottle, Stamford	Otolarnology
Thomas J. Danyliw, Brookfield	Family Medicine
Carl J. Dila, Stamford	Neurosurgery
Vincent P. Donnelly, Bridgeport	Surgery
John B. Famiglietti, Brookfield	General Surgery
H. Martin Fuchs, Norwalk	I.M.-Gastro.
George J. Geanuracos, Fairfield	OB/GYN
Peter A. Goodhue, Stamford	OB/GYN
Stanley E. Goodman, Norwalk	E.N.T.
George Gorun, Stamford	Plastic Surgery
Joseph Gromults, Jr., Stamford	Internal Medicine
Bertram H. Grossman, Norwalk	Pediatrics
James F. Guthrie, Norwalk	Colon/Rectal Surgery
John R. Iacovino, Norwalk	Pulmonary Disease
James W. Innes, Greenwich	I.M.-Gastro.
Stephen R. Katz, Fairfield	OB/GYN
Maria Khan, Danbury	Anesthesiology
Jerome J. Klein, Norwalk	I.M.-Endocrinology
Neil C. Klein, Stamford	I.M.-Gastro
Stanley J. Kramer, Stamford	Pediatrics
Ronald H. Levin, Bridgeport	Internal Medicine
Peter H. Maher, Greenwich	I.M.-Cardiology
Charles R. Marshall, Cos Cob	Phy.Med. & Rehab.
G. William McQuade, Bridgeport	Surgery
Bernard O. Nemoitin, Stamford	Occ. Med. Surgery
John C. Olsavsky, Bridgeport	Radiology
Melvyn Rapoport, Fairfield	OB/GYN
Ronald A. Ripps, Danbury	Orthopedic Surgery
Pasquale Santagata, Stamford	Anesthesiology
Francis J. Scarpa, Stamford	Surgery
Margaret A. Sennett, Greenwich	Internal Medicine

FAIRFIELD COUNTY DELEGATES (cont.)

Marjorie Shafto, Danbury	Family Practice
Bernard J. Sherlip, Bridgeport	Family Practice
Cleo I. Siderides, Stamford	Pathology
Denis M. Sivak, Westport	OB/GYN
Harry B. Soletsky, Brookfield	I.M. & Cardiology
Marc P. Storch, Westport	OB/GYN
Edwin F. Trautman, Trumbull	Public Health
Vincent J. Tumminello, Stamford	Urology

HARTFORD COUNTY DELEGATES (42)

A. Ezra Andrews, Hartford	Anesthesiology
David J. Belman, New Britain	Orthopedics
Gerald I. Blank, Hartford	Internal Medicine
Avrum H. Blitzer, Hartford	I.M.-Gastroenterology
G. Peter Bloom, Hartford	Surgery
T. Blumer, Southington	Pediatrics
Cornelis Boelhouwer, Hartford	Psychiatry
Antoinetta M. Capriglione, New Britain	Ped./Neonat.
Eugene J. D'Angelo, Southington	Family Practice
Evans H. Daniels, Hartford	Family Practice
George M. Donahue, Enfield	Internal Medicine
Richard J. Fauliso, Hartford	Internal Medicine
Brendan M. Fox, Hartford	Urology
John M. Gibbons, Hartford	OB/GYN
Todd M. Gladstone, New Britain	Ped./Neonat.
Thaddeus Gutkowski, South Windsor	OB/GYN
David M. Hild, Hartford	Internal Medicine
Monroe Himelstein, Hartford	General Surgery
Carl F. Hinz, Farmington	Internal Medicine
Katherine C. Ill, New Britain	Chronic Disease
Kenneth T. Johnson, New Britain	Surgery
Witold Kawecki, New Britain	Psychiatry
David E. Kay, Bristol	Radiology
R. Leonard Kemler, Hartford	Thoracic/Cardiovas. Surg.
Robert A. Kramer, Newington	I.M.-Cardiovas. Dis.
Michael Krinsky, Bloomfield	Neurology
Anthony F. LaSala, Hartford	Cardiology
H. John Malone, Manchester	Pediatrics

HARTFORD COUNTY DELEGATES (cont.)

Fred Mantel, Bloomfield	Colon/Rectal Surgery
Robert U. Massey, Farmington	Internal Medicine
Burton M. Meisner, Manchester	General Surgery
John B. Monaco, Rocky Hill	OB/GYN
Lawrence D. Mullany, Hartford	I.M.-Infectious Dis.
Manny Myerson, Hartford	E.N.T.
John J. O'Brien, Hartford	Orthopedic Surgery
Sundaram V. Ramanan, Hartford	I.M.-Hematology
John D. Rixon, West Hartford	Internal Medicine
Steven E. Selden, Bloomfield	Orthopedic Surgery
Lawrence E. Sereda, Hartford	Child Psychiatry
Paul A. Shapiro, Hartford	I.M.-Gastro.
Arthur D. Wolf, Hartford	Internal Medicine
Edward J. Zebrowski, Plainville	Family Practice

LITCHFIELD COUNTY DELEGATES (7)

Thomas Danaher, Torrington	General Surgery
Peter A. DiCorleto, Winsted	Internal Medicine
William A. Handleman, Torrington	I.M.-Nephrology
Ernest Izumi, Winsted	Pathology
Steven R. McCoy, Torrington	Orthopedics
Evan P. Provisor, Sharon	Gen'l. & Vas. Surgery
Michael R. Tesoro, Sharon	OB/GYN

MIDDLESEX COUNTY DELEGATES (6)

Albert W. Bertuch, Middletown	Ophthalmology
James Brown, Middletown	Internal Medicine
Vincent Catrini, Middletown	General Surgery
Bernard F. Sheehan, Old Saybrook	Family Practice
Juan Sosa, Middletown	Psychiatry
John Stanford, Essex	Family Practice

NEW HAVEN COUNTY DELEGATES (37)

I. Willard Abrahams, Meriden	Ophthalmology
Abraham E. Alpert, Hamden	Radiology
John P. Amodeo, New Haven	General Surgery
Stephen Brenner, New Haven	Internal Medicine
Birur G. Chandra, Milford	Allergy
Suk C. Chang, Waterbury	Psychiatry
Lycurgus M. Davey, New Haven	Neurological Surgery
Philip Dennen, Waterbury	OB/GYN
Louis M. DeNegre, Milford	Radiology
Edward Dunn, Waterbury	General Surgery
Edward L. Etkind, New Haven	Internal Medicine
Allen W. Fanslow, Stratford	Anesthesiology
Howard Fink, Milford	Pediatrics

NEW HAVEN COUNTY DELEGATES (cont.)

Ellen R. Fischbein, Cheshire	Psychiatry
Saul A. Frankel, New Haven	Neurosurgery
Edward Gerber, Naugatuck	General Surgery
Isaac Goodrich, New Haven	Neurosurgery
Michael Kashgarian, New Haven	Pathology
Mark L. Kraus, Waterbury	Internal Medicine
William Maniatis, New Haven	Surgery
Christopher M. McLaughlin, Woodbridge	Orthopedics
Mary Jane Minkin, New Haven	OB/GYN
Ferdinand J. Montegut, Ansonia	Thoracic & Vas. Surg.
Robert L. Mullin, New Haven	Card. Surgery
F. Manouchehr Nezhad, Waterbury	Internal Medicine
John Redmond, Wallingford	Ophthalmology
Boris G. Rifkin, New Haven	Psychiatry
Fernando P. Saracco, Hamden	Internal Medicine
Carl W. Scheer, Meriden	Radiology
Daniel S. Schwartz, Meriden	Gen'l. & Vascular Sur.
Anthony Scialla, Hamden	General Surgery
Morton H. Silberstein, New Haven	Psychiatry
David M. Silverstein, Derby	Neurosurgery
Harold Stern, New Haven	Thoracic & Cardiovas. Surg.
Herbert E. Weisberg, Waterbury	Radiology
Steven Wolfson, New Haven	Cardiology
Andrew S. Wong, New Haven	Ophthalmology

NEW LONDON COUNTY DELEGATES (10)

Tom P. Bell, Norwich	Vas. & Gen'l. Surgery
Carl Conrad, Colchester	Family Practice
Thomas Cook, Norwich	Dermatology
Louis Coulson, New London	Orthopedic Surgery
Stephen F. Heller, Groton	Internal Medicine
Hugh Lena, New London	Gen'l. Surgery
Robert A. Linden, Niantic	Internal Medicine
Thomas J. Masterson, Norwich	Orthopedic Surgery
Peter J. Rosenberg, Norwich	Otolaryngology
Joseph Zeppieri, New London	Orthopedic Surgery

TOLLAND COUNTY DELEGATES (2)

Brendan G. Magauran, Enfield	Family Practice
Charles G. O'Connell, Vernon	OB/GYN

WINDHAM COUNTY DELEGATES (4)

Arturo Diaz, Putnam	Anesthesiology
Kenneth R. Dardick, Storrs	I.M.-Family Practice
Marjorie Petro, Willimantic	Internal Medicine
Sherman Waldron, Thompson	Family Practice

New AMA Ethics Opinion Cited By Courts

On March 15, 1986 the AMA Council on Ethical and Judicial Affairs issued a new opinion on "Withholding or Withdrawing Life Prolonging Medical Treatment." That opinion is set forth in full below. In part, that opinion provides that "Life prolonging medical treatment includes medication and artificially or technologically supplied respiration, nutrition or hydration."

Since the opinion was issued, three courts have issued opinions authorizing the removal of feeding tubes, recognizing in each case that the patient could die as a result of such removal. In each case the court cited the opinion by the AMA Council on Ethical and Judicial Affairs in support of their opinion.

In the *Matter of Jobes* (Docket No. C-4971-85E, Superior Court of New Jersey, Chancery Division-Morris County; April 23, 1986) is a trial court decision that authorizes the removal of a feeding tube from a patient in a persistent vegetative state who is permanently devoid of all cognitive functions but has some brain stem activity controlling such functions as sleeping, waking, breathing, body temperature, and blood pressure. The patient does not require a respirator.

In *Bouvia v. Superior Court* (Case No. Bo19134, Cal. Ct. of App., April 16, 1986) the court allows the removal of nasogastric tubes from a patient who requires the tube for feeding, but who is neither comatose nor terminally ill, having a life expectancy of 15-20 years. The patient has been afflicted with severe cerebral palsy from birth and also suffers from arthritis. The patient is quadriplegic and completely bedridden. The patient is completely dependent upon others for all of her needs, including feeding. She cannot retain solids, and because a weight loss could be life-threatening to this patient, a nasogastric tube was inserted without her consent.

In *Corbett v. D'Alessandro* (Case No. 85-1052 Fla. Dist. Ct. of App., April 18, 1986) the court allowed the removal of nasogastric tubes in a case involving a 75-year-old patient who had been in a persistent vegetative state for over three years, with no reasonable prospect for regaining cognitive brain function. The courts entered the order despite the clear language of the Florida "Right to Decline Life-Prolonging Procedures Act" (Chapter 765, Fla. Stats.) which provides in part: "The term 'life-prolonging procedure' does not include the provision of sustenance or the administration of medication or performance of any medical procedure deemed necessary to provide comfort care to alleviate pain."

— AMA Hospital Medical Staff Section
Newsletter, July 1986.

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

FAMILY PRACTITIONERS AND OBSTETRICS

To the Editor: As board-certified members of The American Academy of Family Practice, active in the practice of obstetrics, we were interested in the article in the January issue by Dr. Wachsman on the liability issues of obstetrical practice. The article was relevant and most helpful.

However, we must object to his observation that "the day of the general practitioner dabbling in obstetrics has hopefully become passe." Family Practice has been a board-certified speciality since 1970 with obstetrical training as a prerequisite to board certification. As a result of our residency training programs, we now have competent, well-trained family physicians performing normal vaginal deliveries in large numbers in every region of the country. We agree with Dr. Wachsman's observations and recognize that care, attention, and adequate training are essential for the practice of modern obstetrics. However, the implication that obstetricians exclusively should perform deliveries has, to use his own phrase, "hopefully become passe."

It is of some note that the medical disasters reviewed in his article refer to situations managed by *obstetricians,* not family physicians. It is our opinion that obstetricians and family physicians must be cautious, keep abreast of new developments, and continue to provide the best quality obstetrical care possible. In the best of circumstances, these two disciplines will be partners in that effort.

Dewees H. Brown, M.D., FAAFP, Director
Middlesex Memorial Hospital
Family Practice Residency Program
Middletown, CT

Joseph E. Fuller, M.D., FAAFP
Old Saybrook, CT

The above letter was referred to Dr. Wachsman, who offers the following reply:

To the Editor: I read with great interest and appreciation the letter by Dr. Brown, commenting on the specialty of Family Practice. I am aware that Board Certified Family Practitioners do engage in obstetrical practice and receive good training which allows them to perform normal vaginal deliveries. My great concern is for those individuals who, trained in the delivery of normal vaginal deliveries, assume responsibilities far beyond their capabilities. My reference to "the day of the general practitioner dabbling in obstetrics has hopefully become passe" refers to those physicians not Board Certified in the specialty of Family Practice and are otherwise unqualified to render obstetrical care.

While it is of some note that the medical disasters which I refer to in my article deal with obstetrical situations my intent was not to imply that those engaged in the practice of obstetrics and gynecology were the only ones who would find themselves in such precarious circumstances. Many of these so called disasters occur when a physician, who is not adequately trained in the care and treatment of obstetrical patients, practices in a manner contrary to good and accepted standards of medical care. While I am uncertain as to the context of Dr. Brown's use of the word "cautious" I certainly concur that all physicians, regardless of specialty maintain currency through continuing education and participating at conferences, workshops and seminars. Again, I wish to thank you for your interest in my article and do hope that the specialty of Family Practice continues to provide the highest quality education for its physicians.

Harvey F. Wachsman, M.D., J.D.
Great Neck, NY

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

AMBULATORY CARE

Position open full or part-time for physician for ambulatory care center in Enfield, CT. Contact Richard Stevens, M.D., Medical Director, 15 Palomba Dr., Enfield, CT. (203) 745-1684.

Physician with primary care/ambulatory care/emergency medicine experience and background, for part-time position in Ambulatory Care Center. Send curriculum vitae to: Medical Director, Immediate Health Care, 4490 Main St., Bridgeport, CT 06606.

EMERGENCY MEDICINE

Full-time position for American trained physician in community hospital in NW Connecticut. Send CV to Lawrence Ward, M.D., Winsted Memorial Hospital, Winsted, CT 06098.

Full time position available at Department of Medicine, Park City Hospital, Bridgeport. BC/BE in Emergency Medicine preferred. ACLS, ATLS required. Competitive Salary, Flexible Schedule. 25,000 ED visits/per year. Send Curriculum Vitae to B.A. Ward, M.D., Park City Hospital, 695 Park Avenue, Bridgeport, CT 06604.

FAMILY PRACTICE

For Sale. Family practice, no Pediatrics. Excellent location in southern Fairfield County, CT. Good opportunity for Spanish speaking physician. Please send replies to CSMS, c/o FP/QQ.

Young, board-certified family physician seeks same to join growing practice on a shared time basis; pediatric interest desirable. If you are seeking to reconcile a rewarding clinical practice with family responsibilities, please forward your CV to Kathleen Ljungquist, M.D., 416 Highland Ave., Cheshire, CT 06410.

Seeking a Family Physician BC/BE who has compassion and a caring personality to join a seventy-year-old Family Physician in his established practice of over forty years, in N.W. Connecticut. Excellent hospital facilities and good family living region. Please respond to CSMS, c/o FP/TT.

GENERAL PRACTICE/INTERNAL MEDICINE

Licensed Physician, part-time, competent and conscientious. Two days a week. Experience helpful. New Haven area. Send resume to CSMS, c/o GP/UU.

INTERNAL MEDICINE

CARDIOLOGIST. BC/BE. Needed in busy invasive and noninvasive cardiological practice. Please send CV to Stephen T. Sinatra, M.D., F.A.C.C., 483 West Middle Turnpike, Manchester, CT 06040. (203) 643-5101.

Internist wanted, part or full-time for Yale University and West Haven VA Hospital, academic or clinical position, start July 1, 1986 or mutual convenience. Responsibilities will be attending on medical, geriatric, and rehabilitation services and teaching PA's, students, and trainees. Contact, Chief, Geriatric and Extended Care Section/111-C, West Haven, VA Hospital, West Haven, CT 06516. 932-5711 ext. 341 or 244.

MISCELLANEOUS

Staff Physician. Masonic Charity Foundation is currently seeking a physician to join the staff at it's 650 resident multi-licensed JCAH approved Wallingford Campus which includes a 150 unit continuing care retirement community. Geriatric experience preferred but will consider internists and new graduates. Standard workweek with rotation of evening and weekend call. Excellent work environment, central Connecticut location, and full range of employee benefits. Salary will be commensurate with experience. Please send curriculum vitae with salary requirements to: Dr. Erlinda Rauch, Medical Director, Masonic Charity Foundation, P.O. Box 70, Wallingford, CT 06492. An Equal Opportunity Employer.

Office space to share starting July 1, 1986. Looking for physicians to timeshare a large office with me. 1,750 sq. ft.; 30-seat waiting room; ample on-premises parking in West Hartford center. Perfect for primary or satellite office. Please call 521-6160.

OBSTETRICS/GYNECOLOGY

Excellent opportunity for progressive BE/BC Obstetrician/Gynecologist to establish practice at the Family Childbirth Center. Arrangement to be negotiated to ease the cost of a start-up practice. For information call 787-2041 or send CV to Family Childbirth Center, 40 Temple St., New Haven, CT 06510.

PEDIATRICS

Seeking a board certified or board eligible pediatrician for either a solo or group practice in the Northeastern Connecticut area. Please send reply to CSMS, c/o PED/XX.

PRIMARY CARE

Internal Medicine/Family Practice trained physicians BE/BC to join our nationally recognized physician group practicing aggressive clinical medicine in six physician-owned ambulatory primary care centers surrounding Hartford and in Norwalk, CT. IM/FP residents rotating through our centers provide teaching opportunities. Send CV to Gregg Grinspan, M.D., Immediate Medical Care Centers, 850 Silas Deane Highway, Wethersfield, CT 06109, or call (203) 721-7393.

Physician. A Connecticut license required to join established primary care practice in New London-Norwich area. Opening for full or part-time. No night calls. Excellent income opportunity. No investment required. Please call 443-4255 or Kathy Williams or Kathy George at Barun Basu Associates, 309 Captains Walk, New London, CT 06320.

PHYSICIANS WISHING TO PRACTICE IN THE STATE OF CONNECTICUT

EMERGENCY MEDICINE

Sept. '87. Age 41. Presently in practice. FLEX. AB elig. MD, Meharry Medical College, Nashville, TN. Int., Hubbard Hospital, Nashville; Res., Hubbard Hospital (General Surgery). Prefers institutional type practice in a large-sized community. Write, William T. Carter, Jr., M.D., 2252 MCDEC Quantico, VA. 22134.

FAMILY PRACTICE

March '86. Age 37. Licensed in Connecticut. MD, B.J. Medical College, Gujrat State, India; Int., B.J. Medical College affiliated hospitals; Res., Maelor General Hospital, Wales, United Kingdom (Gen. Surg.) and various hospitals approved by Royal College of Obstetricians and Gynecologists of England, (OB/GYN). Prefers family practice in group, solo, or institutional medicine. Write, Dr. V. Patel, M.D., 155 Bull Hill La., West Haven, CT 06516 or call (203) 934-8876.

GENERAL PRACTICE

Availability negotiable. Licensed in Connecticut. Age 34. Nat'l bds. AB cert. MD, UConn, Farmington; Int., Griffin Hospital, Derby; Res., Conn. Valley Hospital, Middletown. Also interested in psychosomatic medicine and rehabilitation medicine. Prefers group, associate, institutional or industrial type practice. Write, P.O. Box 239, Higganum, CT 06441.

Jan. '86. Age 47. Licensed in Connecticut. FLEX. AB elig. MD, Cairo University Medical School, Cairo, Egypt; Int. and Res., Rhode Island Medical Center and Iowa University Hospitals; Fellowship, Indiana University School of Medicine. Desires general medicine position in institutional or industrial type practice in a small to medium-sized community. Write, CSMS, c/o MG/G.P.

GENERAL SURGERY

July '86. Age 31. FLEX. AB cert. MD, Bombay University, Bombay, India; Int. and Res., Brooklyn Hospital, Brooklyn, NY; Fellowship, Wayne State University, Detroit, MI (Thoracic & Vascular Surgery). Prefers solo, group, associate or institutional type practice in a medium-sized community. Write S. Patel, M.D., 25824 Lincoln Terrace Dr., Oak Park, MI 48237.

INTERNAL MEDICINE

July '86. Age 30. Nat'l bds. AB elig. MD, Northwestern Medical Center, Chicago, IL; Int. and Res., Northwestern University (McGraw Medical Center). Prefers a group type practice in a small to medium-sized community. Write, Stephen M. Spear, M.D., 215 E. Chicago Ave., Apt. 2305, Chicago, IL 60611.

Immediately. Age 40. Presently in practice. Nat'l bds. AB cert. MD, New York University; Int., Maimonides Medical Center, NY; Res., Beth Israel Medical Center, NY. Prefers permanent part-time or full-time without major coverage responsibilities. Would also cover office hrs/nursing home rounds for busy group. Write CSMS/ c/o SN/IM.

Oct. '86. Age. 31. FLEX. AB elig. MD, University of Witwatersrand, So. Africa, Int., Wanganui, New Zealand; Res., St. Ann's Hospital, London, Old Church Hospital, Rush Green Hospital, Barnet General Hospital, London, England. Prefers group type practice. Write, Stephen J. Stanton-Reid, M.D., 207 Greystone La., Apt. 19, Rochester, NY 14618.

Seeking BC/BE Internist to walk into retiring partner's practice. Office located across the street from Manchester Memorial Hospital, Manchester, CT. Guaranteed base salary with incentives. Call (203) 646-1167 or send to Daniel Tardif, M.D., 56 Haynes St., Manchester, CT 06040.

ENDOCRINOLOGY. March '87. Age 30. Nat'l bds. AB cert. MD, McGill University, Montreal, Canada; Int. and Res., Johns Hopkins Hospital, Baltimore, MD; Fellowship, MRC Neurochemical Pharmacology Unit, Cambridge, England and Johns Hopkins Hospital. Prefers a group type practice. Especially interested in HMO-based practice with part-time affiliation with a teaching hospital. Write, Helene M. Langevin, M.D., 2241 Rogene Drive, Apt. T2, Baltimore, MD 21209.

HEMOTOLOGY/ONCOLOGY. July '87. Age 34. Nat'l bds. AB Cert. MD, Albany Medical College, NY; Int., Naval Hospital, Bethesda, MD; Res., and Fellowship, Naval Hospital, San Diego, CA. Prefers solo, group or institutional type practice in a medium to large-sized community. Write John J. Nanfro, M.D., 9118 Kirkdale Rd., Bethesda, MD 20817.

NEUROLOGY

Sept. '86. Age 34. FLEX. AB elig. MD, University of Bombay, India; Int., Grant Medical College, Bombay; Res., University of Tennessee, Memphis, TN. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Kirit C. Shah, M.D., 50 S. Morrison, Apt. #7, Memphis, TN 38104.

OPHTHALMOLOGY

Nov. '85. Age 31. Presently in practice. Nat'l bds. AB cert. (PED); AB elig. (OPTH). MD, Chicago Medical School, Chicago, IL; Int. and Res., North Shore University Hospital; Fellowship, SUNY-Downstate Medical Center. Mostly interested in a group practice in general ophthalmology. Write, Andrew E. Gewirtz, M.D., 64 Pond Rd., Apt. G-3, Woodbury, NY 11797.

PATHOLOGY

Board certified Pathologist, AC-CP, available in Connecticut for Locum Tenens or part-time position. Please phone (203) 224-5584.

Sept. '86. Age 38. Licensed in Connecticut. Presently in practice. Nat'l bds. AB cert. MD, University of North Carolina; Int. and Res., Rhode Island Hospital, Providence, RI; Res., (Path) Yale New Haven Hospital. Prefers solo, group, associate or institutional type practice. Write, Richard N. Pierce, M.D., 14313 Piccadilly Rd., Silver Spring, MD 20906.

PRIMARY CARE

June '86. Age 45. Licensed in Connecticut. Presently in practice. AB elig. MD, Tehran University; Int., Pahlavi Hospital; Res., Maclean-Metropolitan-St. Elizabeth-Jewish Memorial Hospitals. Prefers solo type practice. Write, Zekrollah Hedayat, M.D., P.O. Box 425, Herkimer, NY 13350.

UROLOGY

July '87. Age 30. Nat'l bds. MD, Bowman Gray; Int. and Res., Medical College of Virginia. Prefers a group type practice in a medium-sized community. Write Steven E. Marks, M.D., 9207 Groundhog Dr., Richmond, VA 23235.

July '87. Age 30. Nat'l bds. AB elig. MD, University of Texas Medical School, Houston; Int. and Res., University of Texas affiliated Hospitals. Prefers group type practice in a medium-sized community. Write CSMS, c/o RD/UROL.

A Half Century of *Connecticut Medicine*

DAVID F. MUSTO, M.D.

Fifty years ago the medical profession felt particularly vulnerable. The danger was not just the bad economic conditions of the Great Depression, although many physicians found themselves with straitened resources due to the inability of their patients to pay for medical care. The economic catastrophe was also the background for a popular movement to change the very nature of medical practice. Proponents called it compulsory health insurance, but the American Medical Association named it "state medicine" which, in its most alarming form, would limit patients in their choice of physician and turn over the control of practicing physicians to a third party, perhaps to non-medical bureaucrats in Washington. The private practice of medicine which had weathered the competition of cults such as homeopathy in the 19th century, the surplus of physicians created by a multitude of shoddy medical schools at the turn of the century, and the disorganization of practitioners who eventually were gathered together by a revitalized AMA, now was challenged by the fear of a government take-over. Such a move was necessary, some reformers claimed, to redistribute and improve the delivery of medical services.

The Depression was so severe that traditional voluntary methods for helping the poor and unemployed were scrapped in favor of government intervention. A myriad of federal agencies, the WPA, PWA, NRA and so on were aimed at relief of the unemployed. Labor unions were aided by new laws, court decisions and the National Labor Relations Board; the stock market was stabilized through the Securities and Exchange Commission and bank deposits were underwritten by the Federal Deposit Insurance Corporation. The government also looked at deficiencies in medical services for the indigent—and others—and considered the alternatives.

The AMA responded vigorously to suggestions that some form of health insurance be included in the innovation which would be called "social security." The Roosevelt Administration with its strong support both in Congress and at the polls, and its penchant for creative approaches to national problems, put organized medicine on the defensive. Who knew what "that man in the White House" would do? But not just the Federal government had the medical profession in its sights. Several states began to consider some form of compulsory health insurance. During World War One, the AMA had convened its first special meeting of the House of Delegates. Now, in the midst of its own war, a second special meeting was called for February, 1935 to respond to political threats and to intensify the profession's awareness.

GEORGE BLUMER, M.D.
1872 - 1962

A New Journal

In May of 1935, a few months after the special meeting in Chicago, the Connecticut State Medical Society convened for its one-hundred and forty-third annual meeting. The delegates arrived with a strong feeling that the state society had to improve its organization in order to keep track of the whirl of medical legislation and to maintain contact with the membership. Possibly the time had come when the Society should provide for an office with a paid administrator and perhaps even inaugurate a periodical which could convey recent improvements in therapeutics,

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DAVID F. MUSTO, M.D., Professor Child Study Center, Psychiatry and The History of Medicine, Yale School of Medicine, New Haven, CT.

review the status of rapidly changing government programs, and generally improve communications. The President was directed to appoint a committee to report on such questions. Chaired by the memorable Dr. Herbert Thoms, the Committee recommended the establishment of an office for the State Society, an Administrative Secretary, a Legislative Secretary and a Secretary on Scientific Work. The latter would, among other duties, edit the new journal, a quarterly which would replace the annual*Transactions.*[1] In 1936 the House of Delegates unanimously approved the re-organization and, in order to pay for these new offices and functions, courageously voted to raise the dues for annual membership in the State Society by twenty-five per cent, that is, from four to five dollars.

Council deliberations on the new journal, originally to be entitled the "Quarterly Bulletin of the Connecticut State Medical Society," seems to include reassurances that enough material could be found to fill four issues a year. The May issue would contain a directory of members, in August minutes of the annual business meeting and reports to the House of Delegates would be published; November's issue would include comprehensive abstracts of all papers presented before the Connecticut Clinical Congress (an annual scientific meeting hosted by Yale School of Medicine in September); and papers of "conspicuous merit" presented during the past year before the State Society or any of the County associations could fill out the February issue.[2]

Stanley B. Weld, M.D.

The *Journal of the Connecticut State Medical Society* flourished under its first editor, Dr. Stanley B. Weld (1890-1979) of Hartford. After his retirement as Editor in 1958, Dr. Weld wrote of the *Journal's* evolution from a quarterly to a monthly publication in January, 1938 and its steady growth thereafter.[3] For several years Dr. Weld took off Thursdays to travel around the state looking for advertisers. During the entire 22 years of his tenure, Dr. Weld did the paste-up of the dummy for the printer, usually in his own home. He became a national expert on the problems and opportunities of state medical journals—all the while maintaining his practice.[4]

After Dr. Weld ended his editorial career, the *Journal* was renamed *Connecticut Medicine*. After a brief stint by Dr. David T. Monahan, Dr. Denis S. O'Connor served as Editor for four years. The successor to Dr. O'Connor was Dr. Louis H. Nahum, a prominent cardiologist whose careful and discriminating editing became over a decade familiar to contributors.[5] In 1972, he was succeeded by Dr. J. Alfred Fabro who continued the distinguished tradition until his retirement a year ago. The incoming Editor is Dr. Robert U. Massey, former Dean of the University of Connecticut School of Medicine and a keen student of the humanities as well as of medicine. We are fortunate that a person of his stature has accepted this position, giving us good reason to expect that the *Journal* will enter its second fifty years under a leadership worthy of its history. For anyone who has worked with *Connecticut Medicine* during the past 36 years, it is impossible not to feel gratitude toward the Assistant to the Editor, Mrs. Vivian C. Feriola whose devoted skills and thoroughness have been a welcome encounter to many an author.

STANLEY B. WELD, M.D.
1890 - 1979

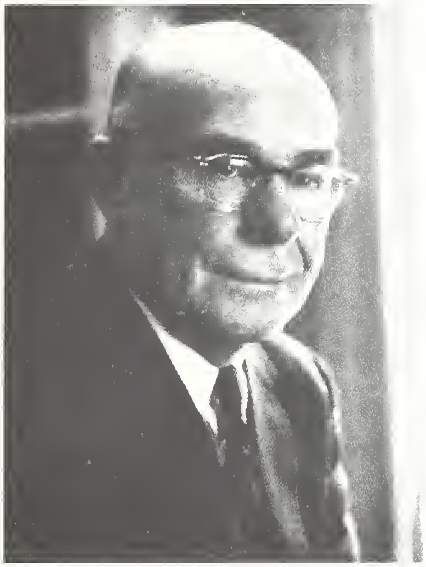
Themes and Controversies

Reading the first few years of the *Journal* is a fascinating experience. Themes, like the best way in which to deliver medical services, remain as vital today as in the hectic battle against "state medicine," while other events, like the introduction fifty years ago of the first antibiotic, the sulfas, remind us that the last half-century has revolutionized the treatment of disease and the very nature of everyday practice.

When Dr. Charles H. Turkington of Litchfield retired as President of the State Society in 1938 he sought to give an historical perspective to contemporary problems of the profession by quoting a description of turbulent times a century earlier. The process is repeated here with a quote from Dr. Turkington who said:

> ". . . We are facing great social and economic changes and, with these, medicine itself is undergoing a change. We, as physicians, are having our imperfections brought to light. We are on the carpet. Not only are we badgered by members of our own profession, but the public and the press seem to have joined in the condemnation. Much evidence of the short-comings of American Medicine has been accumulated."[6]

Connecticut physicians were at times irritated by criticisms of the profession, for Connecticut enjoyed one of the highest levels of health and longevity in the United States. The *Journal* records many instances, though, when both the editor and the leadership of the Society refused to take a rigid or stubborn position on the controversy over the delivery of health care. The Society repeatedly established groups to study issues quietly and carefully. An editorial in the first issue defended several prominent American physicians, such as Dr. Hugh Cabot, who had been severely criticized by some in the profession for advocating reform of the health care system. The *Journal* commented that the intentions underlying the attitudes of Cabot and his colleagues "can only be the good of the people at heart and a desire to protect the individual against hazards to his personal economic security."[7] Out of these debates over health care evolved the now familiar Blue Cross and Blue Shield programs.



CREIGHTON BARKER, M.D.
1892 - 1960

Therapy in the 30s

Treatment of diseases, of course, was frequently discussed in the *Journal* in the form of original reports, reviews of the literature, and articles by nationally famous experts who brought the latest judgment on therapy to scattered Connecticut practitioners. Pneumonia was a common subject: penicillin remained a future miracle, but some progress could be reported in traditional therapy of pneumonia with the development of type-specific antipneumococcic sera. In order for the sera to be maximally helpful, it was believed that the type of pneumococcus afflicting an individual had to be determined immediately upon diagnosis and the appropriate sera given within the first day. Of the 32 types of the bacterium recognized, five types were responsible for more than half of the cases. The State Department of Health could afford to provide sera for two types to physicians upon request. Clearly, this was complex and frustrating, but at the time it was considered a major advance over past treatment which was merely symptomatic and "expectant."[8] Syphilis similarly was a common topic of discussion with elaborate procedures detailed, although hope of cure was not great.[9] One who wrote of the use of sulfa in the treatment of gonorrhea was Dr. Luca E. Celentano whose honored career began years before the founding of this journal and continues still.[10]

Poliomyelitis struck fear into communities, but just what to do to prevent or cure the disease had so far eluded researchers and clinicians. Among the eminent authorities who appeared at the annual Clinical Congress was Dr. Thomas M. Rivers, one of the great names in the eventually successful battle against polio. Dr. Rivers of the Rockefeller Institute for Medical Research, made a suggestion in September, 1936 which was published in the November issue of the *Journal:*

"There is one method of prophylaxis which seems of value during epidemics, the hardening of the nasal mucosa to present a stronger barrier to the virus. Picric acid and sodium alum in 10 per cent solution are mixed and painted on to the nasal mucosa every day during the epidemic and once a week for several weeks afterwards. The results are encouraging."[11]

If polio elicited uncomfortable and questionable treatments, researchers remained apparently unaware of any link between tobacco smoking and lung carcinoma. In the earliest volumes of the *Journal* rather thorough descriptions of lung cancer, a growing cause of death in Connecticut, never alluded to a patient's smoking habits nor to any other possible atmospheric pollutants.[12] One bit of evidence that physicians did not consider tobacco a dangerous product was the presence of large advertisements for cigarettes in the *Journal.* One of the most interesting of the cigarette advertisements was from Philip Morris & Co., complete with references to several medical journals stating that their brand of cigarettes was less irritating than other brands because "diethylene glycol is used as the hygroscopic agent" and not the more common glycerine. A coupon could be clipped from the ad for reprints of the references and two free packs of cigarettes.[13]

Psychiatry was well-represented by articles on widely diverse topics. Sigmund Freud's theories were controversial and several authors took a skeptical view of them, but he was also ably defended by Dr. Marian C. Putnam of New Haven.[14] The Sterling Professor of Psychiatry at Yale, Dr. Eugen Kahn, contributed essays on such subjects as how to quit smoking, who should not marry, and how to relieve anxiety.[15,16,17] The interest in psychiatry seemed to stem from common concerns about personality problems encountered in everyday practice. Every few months a report was issued from the Neuro-psychiatric Institute of the Hartford Retreat by a committee of the State Society encouraging the use of the Institute for institutional treatment of severe mental illness and some forms of alcoholism.[18]

Somewhere between psychiatry and general practice lay the issue of drug abuse. The Society fought for the inclusion of barbiturates as one of the drugs requiring a physician's prescription. The level of opiate abuse, although worrisome to the Society's committee on narcotics, would be almost invisible today. Illicit drug use in Hartford apparently was resolved by a dozen arrests.[19] Although cannabis was mentioned as a substance which also should be under prescription control, no strident alarm was signalled over marijuana during 1937, the year the substance was effectively prohibited by the federal government.

HERBERT THOMS, M.D.
1885 - 1972

Curiosities

A few curiosities also appeared in these pages. In an article reprinted from the *Journal* of the Tennessee Medical Association, an inventor described his machine which could inject oxygen subcutaneously, 500 to 1000cc for an average dose. He claimed this would help pneumonia patients in particular, although anyone with anoxemia or asphyxia could benefit.[20] Conveniently, facing the last page of this article was a full-page advertisement from a New Haven medical supply store illustrating the apparatus and making remarkable claims for it. Of similar interest was an article analyzing temperature, barometric pressure and other climatic parameters at the time of serious illnesses. The death of Calvin Coolidge on January 5, 1933, examined from this point of view, appeared understandable. Similar rapid changes in temperature apparently accompanied Abraham Lincoln's deep depression after breaking an engagement to a young woman. Detailed charts accompanied this interesting article.[21]

In the tradition of 19th century medical journals, Dr. Herbert Thoms described the diagnosis and removal of an ovarian cyst weighing 135 pounds.[22] He acknowledged the aid of an Assistant Resident, Dr. Gustaf E. Lindskog, later chairman of Yale's Surgery Department. As I write this, Dr. Lindskog is preparing in the Cushing Rotunda an exhibit on the history of bronchiectasis, a happy illustration of unbroken productivity.

A Homogeneous Society

The impression I receive from reading the early volumes is of a more homogeneous and compact Society than at present. One reason for this is that most physicians were engaging in a similar kind of private, fee-for-service practice. And, of course, the membership was smaller: about 1,600 in 1935 and nearly 5,200 in 1985.

Although the role of women practitioners was not large, they had a presence, particularly Dr. Kate C.H. Mead who contributed several articles on the health of women to help educate her male colleagues. Writing about the menopause, for example, she pointed out a recent British study which indicated that almost 90% of women passed through the menopause without interference in their occupations by physical or emotional symptoms.[23]

Dr. Herbert Thoms

Of the many personalities who appear in the *Journal*. I would like to mention a few of those who made major contributions to the practice and organization of medicine in Connecticut. I have already alluded to Dr. Herbert Thoms (1885-1972), whose remarkable life combined medical, artistic, historical and public policy interests. Dr. Thoms made contributions to pelvimetry in obstetrics, established a rooming-in program for infants and mothers after delivery and created a natural childbirth program "at a time," Dr. Weld later wrote, "when the administration of drugs in labor had reached an all-time high."[24] He led the battle to overturn the Connecticut laws restricting information on birth-control. He also published several books on the history of medicine in Connecticut and served the *Journal* for many years as a member of the Editorial Board and later as the Literary Editor.

WALTER R. STEINER, M.D.
1870 - 1942

Osler's Disciples: Dr. Blumer and Dr. Steiner

The long shadow of Sir William Osler followed two of the most active members of the Society, Drs. George Blumer (1872-1962) and Walter R. Steiner (1870-1942). Dr. Blumer was born in England but grew up in California where his family had entered the citrus fruit business.[25] He graduated M.D. from Cooper Medical College in San Francisco in 1891 and after internship went to Johns Hopkins Hospital where he was first a surgery house officer under Dr. W.S. Halsted and then a medical house officer under Osler. Following that, he served a year in the pathology laboratory under Dr. William Welch and Dr. Simon Flexner. Quite an education! He was at the University of California medical school in 1906 when he was called to Yale as Professor of Medicine. Named Dean of the School of Medicine in 1910, he served a decade in that post. Somewhat eclipsed by the dramatic tenure of Dean Milton C. Winternitz, Blumer nevertheless had been instrumental in building the groundwork for the enormous expansion in the 1920s, for establishing a college degree as a requirement for admission, for bringing the School through the strains of the First World War and for overseeing the admission of women to the Yale Medical School. Dr. Blumer remained on the faculty until academic retirement in 1939. He maintained an active practice in New Haven until 1942, wrote widely on diagnosis, and was considered a gifted bedside teacher. He had long been a valued member of the Connecticut State Society, served as President in 1920 and, to take one example of the confidence placed in him, was entrusted with chairmanship of a crucial group, "The Committee of Twenty" which set forth in 1938 the Society's position on "principles which should govern the practice of medicine in the State."[26]

Dr. Steiner combined Osler's two great joys, the practice of medicine and the collection and study of books on medical history. Dr. Steiner's father was a physician and librarian, becoming the first librarian of Enoch Pratt Free Library of Baltimore. Steiner came into close contact with Osler when he attended medical school at Johns Hopkins, graduating in 1898 and spent two additional years there in post-graduate training. He entered practice in Hartford where he functioned as a pathologist and as an internist. Elected President of the State Society in 1934, his activities as a librarian and historian were also well known. The Library of the Hartford Medical Society is named after him as is a seminar room at the Yale Medical Library. His portrait hangs in both institutions.[27]

Dr. Creighton Barker

When in 1936 the State Society reached the momentous decision to create the post of executive secretary, Dr. Creighton Barker (1892-1960), an otorhinolaryngologist who was serving as Treasurer of the Society, was the choice. A graduate of Dartmouth and its medical school, he served part-time as administrative secretary for two years, after which he relinquished private practice to give full time to his new role as Executive Secretary until retirement in 1958. During an era of enormous demands within the profession, he had been the animating force behind the growth and influence of the State Society. He was a contact point between the Society and legislators, the public and the rest of organized medicine. Dr. Barker was at times a stern taskmaster, but the results of his efforts were a powerful Society and the gratitude of his colleagues.[28]

As a native of Washington State and graduate of its medical school, I was pleased to see the name of a respected teacher in Seattle, James W. Haviland, among the scientific contributors in the earliest years of the *Journal.*[29] While in post-graduate training, Dr. Haviland wrote several papers with Dr. Francis G. Blake, Professor of Medicine at Yale, on the use of the new miracle-drug, sulfa. Dr. Haviland has had a distinguished career including the Presidency of the American College of Physicians. While preparing this article I was reminded by his retirement in July at age 75 that the era we have been examining for all its remarkable change in the science and organization of medicine spans a single lifetime of practice.

Speculation on the state of medicine fifty years from now would not produce a very likely set of predictions. Will practice be so regimented and rationed by third-parties that it will cease to be a satisfying life of service? Or will treatment become so routinized and uncomplicated in the vast majority of cases that clinical judgment will be irrelevant? At the least, we can feel confident that if our civilization endures, the lifespan will extend further and that diseases will be attacked closer and closer to their roots. In that future, we know that formal communication among physicians will be an essential element in the life of the medical community. We celebrate in this issue of *Connecticut Medicine* a half-century of successful communication and anticipate an equally satisfying centennial.

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The Leading Causes of Death in Connecticut, 1935 and 1984

Cause	Crude Death Rate/100,000 1935	Crude Rate/100,000 1984
1. Heart	296	335
2. Malignant neoplasms	139	211
3. Nephrosis/Nephritis	92	8
4. Cerebrovascular diseases	87	59
5. Accidents (not Motor Vehicle)	77	15
6. Pneumonia	70	28
7. Tuberculosis	45	<1
8. Diabetes	31	16
9. Motor Vehicle	30	15
10. Influenza	9	<1
11. Liver	5	11
Chronic Obstructive Pulmonary Diseases		27
Suicide		9
Crude death rate per thousand	10.6	8.8
Population	1.7 million	3.2 million

Source: Division of Health Planning, Policy and Statistics
Connecticut State Department of Health Services

Physicians and Their Concerns—Then and Now

MARTIN DUKE, M.D.

During the year 1936, the first volume of the *Journal of the Connecticut State Medical Society*, the forerunner of what is currently *Connecticut Medicine*, appeared. On the occasion of this 50th anniversary year issue, it is tempting to compare some of the thoughts and concerns expressed in the early pages of the journal with ideas and problems discussed in the journal a half-century later.

In order to put the year 1936 into perspective, events taking place in the world at that time need be mentioned. Internationally, Italy under Mussolini was expanding its colonial empire into Ethiopia, Hitler and Nazi Germany had reoccupied the Rhineland, the civil war in Spain was serving as a training ground for the major participants of the soon-to-arrive World War II, Stalin's second five year plan for Russia was underway, China and Japan were still at war, Edward VIII had abdicated the throne of England to marry an American divorcée named Mrs. Wallis Simpson, and Henry Dale from England and Otto Loewi from Austria were the recipients of the 1936 Nobel Prize for Medicine for their work describing the chemical transmission of nerve impulses. Closer to home, Franklin Delano Roosevelt had overwhelmed his Republican opponent Alfred Landon to win a second term as President, the Social Security Act establishing a system of old age insurance and pensions was a year old, the United States had demonstrated a desire to remain neutral as Europe was slowly heading towards war, Jessie Owens was the American Olympic hero, and Margaret Mitchell's book "Gone With the Wind" was published and soon to be made into a movie classic.

Citing a long standing problem, the editorial pages in the 1936 journal commented upon a touchy legal issue—the appropriate use of expert medical testimony.[1] Referring to an article in the same journal by Dr. Thomas P. Murdock, the immediate past president of the State Medical Society,[2] the training, skill and economic motives of experts called to give medical testimony were discussed—"I believe that some men have stretched their testimony to favor the side for which they were appearing. I believe that it could be proven that their testimony was molded to suit the particular case." Insurers and members of the legal profession were included in these criticisms. Murdock not only called for better cooperation between the medical and legal professions (a familiar appeal), but also proposed that the state appoint special commissioners who would have the skill and qualifications to obtain, evaluate and present impartial medical testimony. After fifty years, many of these issues are still not resolved, although HB 6134, An Act Concerning Tort Reform, has recently been approved by the Connecticut General Assembly and addresses questions related to attorney contingency fees, countersuits, and (Dr. Murdock would be gratified to know) the qualifications of expert witnesses.

In 1936, the Tumor Committee of the Connecticut State Medical Society wrote[3] how difficult it was "1—to get patients to submit themselves once a year for such (cancer) examinations (and) 2—to enlist the cooperation of the physicians." Towards this end, an association of tumor clinics had been established. However, if physicians of 50 years ago and their present day counterparts were able to converse with each other, they might continue to find themselves bound by a mutual bond of frustration at the obstacles encountered in solving these problems.

Several committee reports also appeared in this first volume of the journal. Included among these were the Committee of Public Health recommending the funding of maternal and child health services with Federal grants and matching state funds,[4] and the Committee on Telephone Listings discussing a code of ethics for physicians in regard to advertising. Other committees involved with Narcotic Drug Addiction and with Public Policy and Legislation have a familiar ring, and indeed, as one reads these 50 year old reports, there is a strong sense of déjà vu about them.

The need to understand the treatment of pneumococcal pneumonia with type specific sera[5] has long since been replaced by concern over infectious disease problems unheard of 50 years ago—noscomial infections, antibiotics, and AIDS and its complications. Although there would be little in common that physicians of today and half-a-century ago could find in discussing such specific

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issues, the desire to learn, an important characteristic of physicians in both eras, would probably transcend such communication difficulties. Indeed, it is of interest and reassuring to observe that education played as important a role fifty years ago as it does today. One cannot help but be impressed with the stature of the speakers at the 12th Annual Congress of the Connecticut State Medical Society held in 1936 and the quality of their presentations as reproduced in the November issue of the first volume of the state journal—Foster Kennedy in neurology, Marion Sulzberger in dermatology, Burrill Crohn in gastroenterology, and Thomas Rivers from the Rockefeller Institute in discussing poliomyelitis. Such conferences took place without the benefit of large honorariums for speakers and the ubiquitous pharmaceutical company support of such programs.

Although recent technologic changes have drastically altered present diagnostic and therapeutic approaches as compared to those used 50 years ago, basic social and human values involved with the care of sick and needy patients have changed little. If we physicians of today find ourselves unable to understand our forebears, it is not because of the passage of time, advanced technology, or a changing political and economic environment, but rather because we have abdicated from or shown lack of involvement in the responsibilities of being concerned and caring individuals. It has been this latter characteristic that has distinguished our profession from others throughout the ages, and has always enabled the past and the present to find a common meeting ground. It is why the voices raised in the first volume of our state journal, although they may have lost much of their technical relevance, can still be appreciated by those who today read the fiftieth volume. It is why sincere physicians of all ages can always understand and appreciate each other, knowing as they do that "the secret of the care of the patient is in caring for the patient."[6]

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SOCIAL SECURITY

The Second Annual Report of the Social Security Board, 1937, has been released recently. Those interested in the insinuation of the Federal Government into medical service will obtain satisfaction, no doubt, from the notation that for Maternal and Child-Welfare Service the Federal Government spent during 1937 almost six million dollars in that field and that state or local funds to the amount of over four million additional dollars have been poured into this same hopper. Also that the United States Public Health Service utilized eight million dollars for the year 1936-1937 and will use another eight million for the year 1937-1938. In addition over one million dollars were used for scientific research and administration. The state and local funds are required to provide sums equal to 69.3 per cent of those advanced by the Federal Government. Offhand this seems like a whole lot of money. It is unlikely that these appropriations will ever be less since the facilities set up for administration will follow the rule governing all such projects. The burden on the taxpayer must necessarily increase and every effort should be made to familiarize these same taxpayers with the fact that all this comes out of their pockets and that they should determine for themselves whether after all it is worth all it costs. —Weekly Roster & Med. Dig., Mar. 12, 1938

—*The Journal,* May 1938

In commemoration of the 50th anniversary of the publication of *Connecticut Medicine* (or, under its original title, *The Journal of the Connecticut State Medical Society*), we are reprinting the following five pieces from earlier issues as a sampling of, and a testimony to, the Journal's achievements.

From the August 1937 issue of the *Journal* of the *Connecticut State Medical Society:*

Experience with Prontosil and Prontylin

DANIEL C. PATTERSON, M.D., F.A.C.S.
Bridgeport

Prontosil and Prontylin are proprietary names for the drugs para-amino-benzine sulfonamide and para-amino-phenyl sulphonamide. The drug is now being offered to the profession by different manufacturers under different names, but as we have used only Prontosil and Prontylin I will confine myself to these terms. Sulfanilamide is the non-proprietary term adopted by the Council of Pharmacy and Chemistry by the A.M.A., though the drug has not been accepted as yet.

Prontylin is put out in powder form and in five grain tablets for oral administration. It is insoluble in water but is readily absorbed. Prontosil is in the form of a red die put out in five c.c. ampules for intra-muscular injection. It is also available now in 50 c.c. rubber capped bottles at half the ampule price.

The story of Prontosil follows somewhat closely that of VonEhrlich's discovery of salvarsan, in that its development was the result of a planned effort to find a chemical substance that would destroy streptococci.

Chemists of the German dye trust in 1934, working with a group of dyes called the azo group, producee the drug, and Domag in 1935 experimented with it on mice. He injected hemolytic streptococci into twenty-six mice and in twelve of these he administered Prontosil by mouth. Fourteen mice were used as controls and these untreated mice were all dead in two days, while none of the mice that received Prontosil died. Since this first experiment Domag's results have been confirmed by numerous other workers.

There seems to be some question still as to the action of the drug, but experiments indicate that it acts as a bacteriostatic agent, inhibiting the growth and actually injuring the streptococci. Phagocytosis then controls the infection.

Unfavorable reactions to the drug are not common. Nausea, headache and lassitude have been reported. We have had two cases in which a leucopenia followed its use. In one case the leucocyte count dropped to 3,400; with 2% Polynuclears. As soon as the drug was stopped the count began mounting and in a few days was normal. I think the leucocytes should be checked frequently in cases under Prontosil treatment.

We have had several cases that showed some cyanosis but it cleared rapidly when the drug was discontinued. Sulphemoglobinemia has been reported following its use, and it seemed more than a coincidence that in a majority of the cases reported magnesium sulphate was being used either internally or as a local application. Long advises

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Read before New Haven County Medical Society, New Haven, Connecticut, April 28th, 1937.

that no magnesium sulphate be used in patients receiving Prontylin.

Marshall and co-workers at Hopkins working on the problem of absorption and excretion of the drug, found that, "In man the substance is excreted in both the free and the conjugated forms."

"Absorption from the gastro-intestinal tract is rapid, being usually complete, or nearly complete in about four hours."

"In patients when large amounts are administered daily in divided doses, nearly 100% may be recovered from the urine, when equilibrium between intake and output is established. It takes three to four days to establish this equilibrium, and the same time to free the body from the drug after it is discontinued; however, I saw an abstract from the Lancet recently in which an investigator stated that in normal animals, 35% of injected sulfanilimide and 49% of the soluble Prontosil was not accounted for. In the case of insoluble Prontosil, 90% was not recovered. It has been found at autopsies that when the dye preparation is used the tissues are quite generally stained."

"In patients with impaired renal function the drug is excreted more slowly and it should be given with great care in cases of renal insufficiency."

"After oral administration sulfanilamide was found in the cerebro-spinal fluid—also in pleural exudate. There was no evidence that the drug was changed in the dog's organism, and its blood concentration suggests nearly complete absorption from the intestines in three to five hours after oral administration."

They find from their studies of blood concentration of the drug that no advantage is gained by injection administration, therefore the oral route when possible appears to be indicated.

Some of the clinical reports that have been appearing in the literature are worth noting. From the Queen Charlotte Hospital, London, comes a very interesting study of the use of Prontosil in cases of puerperal infection. In 1935 ninety cases were treated in the usual manner, with twenty-two deaths,—or 24.4% mortality. During eight months of 1936 sixty-four cases were treated with Prontosil, with three deaths, or a mortality rate of 4.7%. The average stay in the hospital in the Prontosil cases was eighteen days, while in the non-Prontosil cases it was 31.3 days. Of the sixty-four cases, twelve gave a positive blood culture of hemolytic streptococci. Nine of these patients recovered. In 1935, of the ninety cases there were fifteen deaths from peritonitis, while in the sixty-four Prontosil-treated cases in 1936 only one died from peritonitis. Complications were practically absent and none of the cases required re-admission.

Long and Bliss have reported the results of treatment of seventy patients with infection due to beta-hemolytic streptococci. There were four deaths and only one of these was considered to represent failure of the specific therapy. They believe that forty-eight hours is required before the maximum therapeutic effect is obtained,—therefore early administration is important.

We have been using the drug at the Bridgeport Hospital since December 1936, treating over one hundred cases, and have been most favorably impressed with the results obtained. Its action in some cases has been most spectacular, and seemed alone responsible for saving the patients' lives. There have been seventeen cases diagnosed erysipelas, all of which responded promptly to Prontosil therapy. The temperature dropped to normal in from two to four days, and the rash faded rapidly.

A typical case was that of M.S., aged eight months. He was admitted January 21st with an erysipelous rash of one day's duration, that had spread over one leg. Temperature on admission 103; leucocytes 24,550; polynuclear leucocytes 86%. Blood culture negative. Prontosil-2½ cc. was given every four hours for ten doses; then Prontylin grains 1½ four times daily. The temperature had dropped to 99 on the 24th and remained normal from then on. This has been the usual course in all the cases. There is sometimes a secondary rise in temperature, but this has generally subsided in twenty-four hours.

We found on checking the average length of stay in the hospital, against a like number of erysipelas cases treated before the use of Prontosil, that it was just one-half.

At Englewood, our contagious disease hospital, they informed me they have treated over two hundred cases of scarlet fever since the first of January. There has been a drop in temperature to normal in thirty-six to forty-eight hours. The rash has faded rapidly, and peeling has been greatly reduced. Complications have been seen but rarely. There were a few cases that had swollen cervical glands, but none developed otitis. There was one period of ten days in which they were out of Prontosil, and during this time several discharging ears developed. In the cases that were admitted with discharging ears, the discharge stopped within three or four days after Prontosil medication was started. That reduced their period of quarantine from four to three weeks.

Doctor Applebaum reporting for the Meningitis Commission, stated that of 256 cases of bacteriologically proven streptococcus meningitis only 15 recovered. In 12 similar cases treated with Prontosil, 9 recovered.

I have selected a few of our most instructive cases to report. I thought they might be of interest to you.

E.F., age 7; admitted January 5th, 1937.

On January 2nd had burn of left arm. On the 4th skin reddened. Patient sick. On admission to hospital January 5th, temperature 105; pulse 150. Very toxic. 2nd degree burn left arm. Erysipelous rash over arm and shoulder. Prontosil 5 c.c. every 4 hours and Prontylin 5 grains every 4 hours started. January 6th, Temperature 105 in A.M.; 99 in P.M. January 7th, temperature 102 in P.M. January 8th, temperature 99; pulse 90. Condition clearing. January 10th, dishcarged from hospital. No culture obtained.

D.C., age 16 years.

On November 21st, 1936, had submucous nasal resection. On November 29th had fever, sore throat, and rash on arms and legs. Admitted to Englewood Hospital—care of Dr. Stanton Smith on December 1st. Temperature 105. 6,000 units scarlet fever anti-toxin was administered. On the next day temperature dropped to 99. Then began a steady rise to December 8th when it was 106. Blood culture taken on the 9th showed hemolytic streptococci. Prontosil 5 c.c and Prontylin 2 tablets, were given every 4 hours. On December 12th, temperature was normal. His further recovery was uneventful.

M.W., age 28. Case of Dr. C. Griswold.

Admitted Bridgeport Hospital, February 25th, 1937. Delivered by low forceps same day. Course uneventful until February 28th, when she had a chill. Abdominal pain. Temperature 103; pulse 120. March 1st, temperature 104; pulse 136. March 2nd, temperature 104.5; pulse 140. Prontosil was started March 4th, temperature 99. Blood cultures were negative. Prontosil discontinued on March 9th and on March 14th patient developed thrombophlebitis in the left leg. Condition has been slowly clearing up. This patient only received 30 c.c. of Prontosil and 180 grains of Prontylin.

S.H., age 7 years. Case of Dr. M. Cheney.

Admitted Hospital, January 21st, 1937. Illness began January 18th. Sore throat. On the 20th had abdominal pain, vomiting and diarrhea. On the 21st, temperature 102; pulse 120. Leucocytes 51,800. 92% polys. On the 22nd, temperature 105; pulse 140. Leucocytes 83,950; polys 100%. Exploratory laparotomy was done. There was diffuse peritonitis, with thin purulent exudate. A culture of this showed hemolytic streptococci. She was started on Prontosil, 10 c.c. every 4 hours. On January 23rd, temperature was 106; pulse 130. From then until the 28th temperature gradually dropped to 100. She then developed a broncho-pneumonia and the temperature again mounted to 105 and the pulse to 130. On February 13th, she developed bilateral otitis, and though the temperature continued high—being 106 on the 19th—from there it gradually dropped to normal on the 24th, and she made rapid progress to recovery from then on. During her treatment she had 400 c.c. of Prontosil and 450 grains of Prontylin. Blood cultures were negative.

S.R., age 50. Case of Dr. Peters.

Admitted December 29th, 1936—acutely ill from bilateral otitis following a cold. Both ear drums had been incised, but infection spread to mastoids. Temperature 104; leucocyte count 25,500; polys 82%. The temperature continued at 105 until the 8th when a left side mastoidectomy was done. Cultures from the wound showed hemolytic streptococci, though blood cultures were negative. On January 14th, a right side mastoidectomy was done, and Prontosil was started. On January 15th the patient showed signs of meningitis. The spinal fluid showed 874 cells; 90% Polys; and a growth of hemolytic streptococci. The temperature remained at 105 until the 19th when it dropped to 100. It was normal on the 20th and continued so until his discharge on February 7th.

R.L., age 16 years.

Admitted to Hospital, March 4th, 1937. Two weeks previously developed otitis media on right side. This was drained. A few days before admission he showed signs of mastoiditis on right side. Admitted acutely ill. Temperature 104. X-ray mastoid showed sclerosis. On the 5th, temperature 105.5; pulse 112. Right mastoid cells operned and a culture from pus showed hemolytic streptococci. Prontosil 10 c.c. every 4 hours was started. On the 7th, temperature ranged 103 to 104 and blood culture showed hemolytic streptococci. On the 11th, temperature 104.6; leucocytes 12,900, with 70% polys. Prontosil was discontinued, and two Prontylin tablets were given every 4 hours. On the 22nd—11 days later—the temperature dropped from 104 to 99, though the blood cultures were still positive. Temperature again rose to 102 and 104. He was transfused on two occasions. On March 26th the blood culture was negative and the temperature began to gradually subside. On April 10th, blood examination showed 3,900 with only 2% polynuclears, and 76% lymphocytes. He was discharged on April 13th.

W.J., age 65—white—male.

Admitted to Hospital, February 6th. On February 4th scratched his right thumb with a piece of wire at home. He applied local dressing, but on the following night thumb was swollen and tender and small incision was made by his physician. No discharge. On admission to hospital patient extremely sick. Irrational. Temperature 104; pulse 130. Right thumb swollen, dark, and tense. No suppuration. Lymphangitis to above elbow. Started on Prontosil 15 c.c. every 4 hours, and Prontylin 5 grains. On February 7th throat was sore. Soft palate, red and edematous. Temperature 104; pulse 120; W.B.C. 23,000. Blood culture negative. Polys 89%. On the 8th, temperature dropped to 101; pulse to 100. Mental condition was clear. Patient much improved. W.B.C. 14,150; polys 89%. On the 10th temperature went to 104; pulse 120; rales in both bases. Patient semi-comatose and irrational. W.B.C. 24,150. On the 11th temperature had dropped to 100; pulse to 80. The cellulitis of the arm had disappeared and the condition of the thumb was much improved. The patient was discharged on February 20th at which time he was up walking about and had no complaints. During treatment patient had 255 c.c. of Prontosil and 120 grains of Prontylin.

A.O., age 19.

Admitted to Hospital, January 10th, 1937. On January 6th patient barked left shin when he slipped from the runing board of an automobile. On January 8th the leg was stiff and pained considerably. On January 9th it was red, swollen and brawny and he had a high fever. On admission the left leg was red, swollen and very tender. The inguinal glands on the left were enlarged. There was con-

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siderable pain in the lower left abdominal quadrant. January 10th, temperature 105; pulse 90 to 100. Started on Prontosil 15 c.c. every 4 hours. January 11th, temperature 104; pulse 90; W.B.C. 18,250; polys 86%. Urine negative. January 12th, temperature 101-102; pulse 90; culture positive for staphylococcus. January 13th, temperature 100.6; pulse 90. Given Prontosil 10 cc. every 4 hours from 8 A.M. to 8 P.M. Prontylin 10 grains 8 A.M.; 1 P.M. and 8 P.M. On January 14th, temperature 98.4; pulse 90. Prontylin continued. January 15th, temperature 98.4; Prontylin continued. January 16th and 17th, temperature and pulse normal. Last dose of Prontylin on the 17th at 8 A.M.—grains 5. Patient discharged from Hospital, January 17th—recovered. During treat ment was given 235 c.c. of Prontosil; and 100 grains Prontylin.

The dosage recommended is that during the first twenty-four hours of treatment 1 c.c. of Prontosil for each pound of body weight up to 100 c.c. be given. After the first twenty-four hours, half of this amount is generally sufficient, except in cases of septicemia, where the original amount may be given until the blood culture is negative. It is given in divided doses three or four times daily. When Prontylin tablets are also administered the amount of Prontosil can be reduced. We are giving Prontylin to most of our cases at present, and find the results satisfactory. In severe cases, and in patients with nausea, we still use Prontosil. Some manufacturers are recommending large initial doses of the sulfanilamide—up to 80 or 90 grains. This is in order to get quick concentration. It sounds reasonable, but when cyanosis has been produced by much smaller doses I do not believe these large doses are advisable until more is known about the drug. The makers of Prontosil advise 80 grains in 24 hours as the maximum.

The action of sulfanilamide is specific on the hemolytic streptococci and we have seen no benefit from its use where other organisms were involved. Lately I have heard of good results following its use in gonococci infections.

From the November 1937 issue of the *Journal:*

The Place of Cesarean Section

FREDERICK C. IRVING, M.D.
Boston, Mass.

Any obstetrical case that ends with a living, uninjured mother and baby is a success. If the baby is lost or damaged, it is a partial failure, but should the mother die, it is a tragedy. To often Cesarean section, performed for improper reasons or upon unsuitable patients, plays a sinister role in the drama of maternal mortality. In the city of Boston from 1933 to 1935 inclusive, 27 per cent of all deaths associated with the puerperal state followed abdominal delivery.[1] For the year 1928 in the State of California,[2] 24 per cent of all such deaths were subsequent to Cesarean section. During the 3 year period beginning in 1930, the rate in New York City[3] was 15.7 per cent and from 1931 to 1933 inclusive in Philadelphia,[4] it was 13.6 per cent. No city in the United States has yet presented in this regard a more unfavorable picture than that displayed by Boston.

Several factors have produced this high ratio of Cesarean section to all maternal deaths. Too great a value is placed upon the life of the unborn child. Many obstetricians, impelled either by religious motives or by fear of criticism because of possible loss of the infant, perform the classical or lower segment operation upon infected patients after many hours of labor, when the patient's safety would have been protected better by an extraperitoneal Cesarean, a Porro operation, or a craniotomy. The accoucheur often forgets that if the patient lives she may have another child, but should she die, as an individual she is irreplaceable. A second factor is the belief, shared by the laity, that Cesarean section is only another way of having a baby and that abdominal and pelvic delivery are interchangeable, or facultative, as it were. The optimistic or inexperienced operator is reassured by the published accounts of 125 or more Cesarean sections without a death, little knowing that the authors of such reports, often skilled surgeons and possessed of excellent judgment, have avoided infected or manhandled cases,

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From the Department of Obstetrics, Harvard Medical School, and the Boston Lying-In Hospital.

Read at the Clinical Congress, New Haven, Sept. 21-23, 1937.

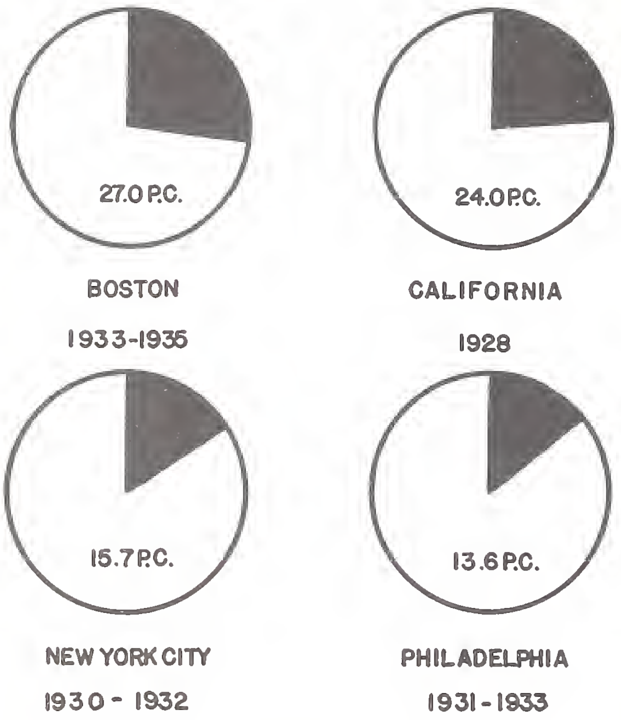

Table 1
The Part Played by Cesarean Section in total Maternal Mortality

and, moreover, that if they did not think it remarkable that they could perform 125 Cesarean sections without a death, they would never have written about it. The fact stands out that even in the clean case with unruptured membranes, not in labor and operated on with the best aseptic technique, there is always a certain risk of peritonitis, since in the puerperium the uterus usually harbors pathogenic bacteria which may gain access to the peritoneal cavity through the uterine wound. Because of this, the operator should weigh well the risk should he elect to deliver by Cesarean section a woman afflicted with a serious medical condition, such as heart disease or diabetes, always remembering that by so doing he is subjecting a patient already ill, not only to the hazards of a surgical convalescence but to the inescapable, intrinsic risk of death attendant upon abdominal delivery. In not a few instances Cesarean section has been performed upon multiparae who have had a number of uneventful pelvic deliveries for the sole purpose of sterilizing them. Such a practice admits of no defense, since sterilization, if it must be done, may be accomplished 3 or 4 months after delivery when involution is complete, with no more risk than attends any simple gynecological operation.

The Frequency of Cesarean Section

In reviewing the literature on Cesarean section, I have confined myself to the six year period beginning in 1931 and extending through 1936, since this time interval coincides with the analysis I wish to make of Cesarean sections at the Boston Lying-in Hospital, and covers my first 6 years as Chief of Staff at that institution.

Table 2
THE INCIDENCE OF CESAREAN SECTION

Author	*Deliveries*	*Cesareans*	*Ratio*
Maxwell (2)	9,727	290	1:33.5
Plass (5)	91,738	955	1:96.6
Daily (6)	17,493	500	1:34.9
Seely (7)	33,988	203	1:16.7
Courtiss & Fisher (8)	31,613	1,000	1:31.6
Montgomery (9)	13,733	229	1:60
Skeel & Jordan (10)	45,650	1,047	1:44
Adams (11)	19,313	217	1:89
Whitehouse Questionnaire (12)	94,235	2,714	1:34.6
Stein & Leventhal (13)	15,136	381	1:39.7.
Stander (14)	5,456	153	1:35.6
Waters & Leavitt (15)	8,852	177	1:50
Palmer (16)	6,533	157	1:41
Lull (17)	23,511	573	1:41
Sackett (18)	18,416	578	1:31.8
	435,394	9,174	1:46.4
Boston Lying-In Hospital			
1925-1930	18,393	688	1:26.6
1931-1936	20,364	584	1:34.9

Table 2 shows the incidence of Cesarean section according to 15 American authors. For comparison is given the incidence at the Boston Lying-in Hospital for the 6 years beginning in 1925, which was 1:26.6 and for the 6 years beginning in 1931, which was 1:34.9. Although our frequency has been considerably greater than the total of the 15 authors, it does not differ greatly from that reported by Maxwell[2] from the University of California, by Daily[6] from the Chicago Lying-in Hospital, by Courtiss and Fisher[8] from the Robinson Memorial Hospital, by Stander[14] from the New York Lying-in Hospital, by Sackett[18] from the same institution prior to 1932, and that given in the report of the White House Conference. It is noteworthy, however, that we have reduced the incidence of Cesarean section by about one-third. Had we continued to perform the operation at the rate current from 1925 to 1930 inclusive we would have recorded 765 operations in the last 6 years or 181 more than were actually performed. Since our gross maternal mortality in Cesarean section in the last 6 years has been 3.1 per cent, it is conceivable that by narrowing our indications we may have avoided over 5 deaths in the past 6 years. This leads to the self evident fact that the easiest way to reduce the number of deaths from Cesarean section is to perform the operation less often.

The Mortality of Cesarean Section

The gross death rate in Cesarean section of all types as determined by compilation of 11,491 cases reported by 17 American authors is 5.8 per cent.

It is interesting to compare the mortality of Cesarean section with that of other common abdominal operations of equal gravity. Dean Lewis[23] gives the mortality after acute cholecystitis with operation as 3.5 per cent. Maes,[24] in Christopher's surgery, reports the death rate from operations for acute appendicitis as 2.7 per cent, while Litzenberg, in the same volume, in 1,421 cases, found the mortality in operations for ectopic pregnancy to be 2.2 per cent. Lockyer[25] reports a 1.6 per cent mortality in supravaginal hysterectomy for fibroids. If these figures are representative, they indicate, broadly speaking, that Cesarean section is about one and one-half times as dangerous as operations on the gall bladder, twice as dangerous as the surgical treatment of acute appendicitis or extrauterine pregnancy and three and one-half times as fatal as supravaginal hysterectomy for fibroids. Granting that this evidence is sound, no conscientious physician can recommend Cesarean section to his patients merely because it affords an opportunity to sterilize them, or because they desire it as a means of escaping the pains of labor, or for any other equally specious reason.

CESAREAN SECTION

Gross Mortality

Table 3

THE MATERNAL MORTALITY IN CESAREAN

Author	*Cases*	*Deaths*	*Per cent*
Plass (12)	2,273	134	5.9
Iowa Questionnaire (5)	1,938	168	8.7
Stein & Leventhal (13)	381	9	2.4
Skeel & Jordan	1,047	75	7.1
Montgomery (9)	229	14	6.1
Sackett (8)	578	25	4.3
Adams (11)	217	10	4.6
Lull (17)	573	39	6.8
Seely (7)	263	9	4.4
Daily (6)	500	5	1.00
Plass (5)	900	63	7.00
O'Connor (19)	429	20	4.6
Courtiss & Fischer (8)	1,000	53	5.3
Maxwell (2)	290	9	3.1
Arnot (20)	356	9	2.5
Bickel (21)	299	22	8.0
Schwarz (22)	218	9	4.1
Total	11,491	673	5.8
Boston Lying-In Hospital			
1925-1930	688	27	3.9
1931-1936	584	18	3.1

The Boston Lying-in Hospital is a semi-public teaching institution with a closed staff that delivers every year in its Hospital and Out-patient Department about 3,500 women, which accounts for approximately one-fifth of all the births in Boston. The private wing of the Hospital is regarded as a separate institution and its statistics have not been used in preparing this report. Our patients are all financially unable to employ a private physician and about 30 per cent are foreign born. Complicated cases are received from outside physicians without question. From 1931 to 1936 inclusive, there were 584 Cesarean sections performed beyond 28 weeks of gestation with 18 deaths, a gross maternal mortality of 3.1 per cent. For the 6 years previous among 688 Cesarean sections there were 27 deaths, or 3.9 per cent. In the past 6 years, therefore, we have reduced our mortality 0.8 per cent, or by about one-fifth.

The Lower Segment Operation Versus the Classical Cesarean

Of late years the lower segment operation has enjoyed a growing popularity. In table 4 is shown the comparative mortality as reported by 15 American authors in the past 6 years. It is apparent, therefore, that the lower segment operation is 4 times safer than the classical.

During the 6 year period in our clinic we have performed 372 classical operations with 8 deaths, a maternal mortality of 2.1 per cent, which is approximately one-third of that reported for the other clinics. There were 168 lower segment operations with 7 deaths, a maternal mortality of 4.2 per cent, or two and a quarter times that recorded elsewhere. At least two deductions are possible. The first is that in the other clinics the classical opera-

Table 4

THE LOWER SEGMENT OPERATION VERSUS THE CLASSICAL

	Lower Segment			Classical		
Author	*Cases*	*Deaths*	*Per cent*	*Cases*	*Deaths*	*Per Cent*
Skeel & Jordan (10)	108	3	2.8	827	63	7.6
Phaneuf (26)	166	1	0.6			
Montgomery (9)	33	1	3.1	180	10	5.5
Sackett (18)	224	6	2.7	303	15	4.9
Greenhill (27)	108	0	0.0			
Lull (17)	103	4	3.8	478	31	6.7
Waters & Leavitt (15)	116	5	4.2	533	2	5.7
Seely (7)	87	0	0.0	105	8	7.6
Daily (6)	461	3	0.6	8	2	25.0
Maxwell (2)	165	0	0.0	113	7	6.1
O'Connor (19)	133	7	5.3	296	12	4.0
Courtiss & Fisher (8)	376	5	1.3	623	48	7.7
Arnot (20)	204	0	0.0	151	7	4.6
Garrison (28)				107	2	1.9
Bickel (21)	183	5	2.7	116	17	14.6
Totals	2,467	40	1.6	3,342	224	6.7
Boston Lying-In Hospital						
1931-1936	168	7	4.2	372	8	2.1

tion has been utilized many times in unsuitable cases. The second deduction is that we have on occasions performed the lower segment operation upon equally unsuitable cases, and this I hasten to admit. The factors which determine the unsuitability of a case for either the lower segment or the classical operation will be considered presently. Our present preference in the lower segment operation is for the vertical incision beginning just above the cervix and extending upward a sufficient distance to allow easy extraction of the presenting fetal pole. This preference is based on a series of 4 cases in which Cesarean section by the transverse uterine incision had been employed in other hospitals and in which the scar ruptured in our institution. All 4 cases were in labor when the accident occurred, and all survived. Of these, one patient had also had a classical Cesarean, but the scar from that operation was found intact and firm. We believe that the lengthening of the lower uterine segment which occurs during labor is likely to pull apart the cicatrix of the transverse incision, but that this danger is much less if the scar is vertical.

The Clean Versus the Questionable Case

Table 5 shows that among 372 classical Cesareans there were 2 deaths from sepsis, or an incidence of 0.5 per cent, while infection caused the death of 5 women, or 2.9 per cent of the 168 patients delivered by the lower segment operation. It is apparent, therefore, that the cases subjected to the classical operation were carefully selected. On the other hand, the loss from sepsis of practically 3 per cent of the patients delivered by the lower segment operation indicates the unsafety, in our hands, of this type of Cesarean for patients who are potentially infected.

Table 5
DEATHS FROM SEPSIS IN CESAREAN SECTION

Type	Section *Cesareans*	*Deaths*	*Per cent*
Lower Segment	168	5	2.9
Classical	372	2	0.5

In an attempt to analyze this situation further I have arbitrarily divided all patients delivered by Cesarean section of both types into two groups, the clean and the questionable. A clean case is considered to be one where not more than 8 hours have elapsed since labor began or the membranes ruptured, where there has been not more than one vaginal examination under aseptic precautions, where there has been no attempt at operative pelvic delivery and no fever over 99.6. Questionable cases are those which do not fulfill these conditions. Table 6 shows the distribution of clean and questionable cases in our 541 classical and lower segment operations. In only three instances in the whole series was the operation performed subsequent to an attempt at pelvic delivery. It will be noted that 325 or 87.1 per cent of our 372 classical Cesareans were clean cases, that only two of these died from sepsis, or 0.6 per cent. On the other hand, 96 or 57.1 per cent, of our 168 lower segment operations were questionable. Four, or 4.2 per cent of them died. It is apparent, therefore, that the lower segment operation does not afford sufficient safety to the woman who is undergoing a prolonged test of labor, a fact which is of the utmost importance. One derives the impression from some articles in the literature that, so long as unmistakeable evidences of infection have not appeared, the lower segment operation may be performed safely at any time during labor. This we do not believe to be the case, Trillat,[29] in an analysis of 110 lower segment operations found the mortality to be 2.3 per cent in 43 clean cases, 5.6 per cent in 53 suspicious cases, and 28.5 per cent in 14 that were febrile. O'Connor[19] reported that the mortality in this type of case was about doubled when there was a prolonged test of labor, bleeding or preeclampsia. Montgomery[9] recorded a mortality of

Table 6
THE CLEAN VERSUS THE QUESTIONABLE CASE. BOSTON LYING-IN HOSPITAL, 1931-1936

	Clean			Questionable		
Type	*Cases*	*Deaths*	*Per cent*	*Cases*	*Deaths*	*Per cent*
Lower Segment	72	2	2.8	96	5	5.2
Classical	324	8	2.2	48	0	0.0
Totals	396	10	2.5	144	5	3.5

Causes of Death

Lower Segment	Lower Segment
Pyemia	Peritonitis 4 A A
Pulmonary embolism A	Vegetative endocarditis A
Classical	Classical
Peritonitis 2 A A	No deaths
Eclampsia 2 A A	
Lobar pneumonia A	
Bronchopneumonia	
Vegetative endocarditis A	
Appendicitis A	

A = Autopsy

0.8 per cent in classical operations done before 12 hours of labor. After 12 hours, the mortality in this type was 8 per cent and in the lower segment operation 3.5 per cent. Couvelaire[30] states that in the study of 436 lower segment operations the death rate was 2.7 per cent when there was no infection and not more than 12 hours had elapsed since the beginning of labor or rupture of the membranes, 6 per cent when conditions were less favorable and 24.5 per cent when there was an elevation of temperature or some complicating pathological state.

We have come to the conclusion that a test of labor should not exceed from 8 to 10 hours, and that it should be conducted, if possible, without vaginal examination. At the end of that time the obstetrician should have reached one of two conclusions: (1) that the patient eventually may be delivered through the pelvis with safety to herself and reasonable safety to the baby, or (2) that delivery through the pelvis is extremely unlikely except at considerable risk to the mother or infant. If a Cesarean section is performed under ideal conditions it may be either of the classical or lower segment type. The lower segment operation is preferable because its published mortality is less. If the obstetrician allows his patient to undergo an extensive test of labor and conditions for pelvic delivery are still unfavorable, he should abandon all thought of either type of operation and arrange for her delivery by an extraperitoneal Cesarean section performed by some competent operator.

The Extraperitoneal Operation Versis the Porro Operation

If the uterine contents are infected, the lower segment Cesarean affords at operation no greater protection against spill and subsequent peritonitis than does the classical Cesarean. Should a peritonitis thus acquired be confined to the lower portion of the peritoneal cavity the process may localize itself and the patient survive. This is equally true if the incision is made in the lower portion of the upper uterine segment, as is the case with all our classical Cesareans. Early in the puerperium in practically every patient delivered by Cesarean section or otherwise, the uterine cavity is invaded by bacteria which may be pathogenic. This has been determined many times by uterine cultures. The utero-vesicle fold of peritoneum, which in the lower segment operation is drawn over the uterine incision, probably acts in many cases as a barrier to seepage through the uterine wound, and herein lies its greater safety. In some of our cases, however, we have found at autopsy that this barrier has not proved effective. For this reason, and because the operation provides no security against spill at the time it is performed, we do not believe that it affords sufficient security to justify its use in the questionable case.

We have performed 23 extraperitoneal Cesarean sections in the last 6 years on patients who were actually or potentially infected, with no deaths. Eighteen were Latzko operations. In five other instances the uterus was marsupialized, that is, stitched to the abdominal wall, opened, its contents evacuated, and still ventrally fixed, closed as in the classical operation with a drain placed to the uterine incision. In Table 7 are shown the results of 391 Latzko operations appearing in the literature. Sixteen patients died, a maternal mortality of 4 per cent. This is better than the gross death rate of classical Cesarean section, regardless of the fact that all such extraperitoneal operations were performed upon potentially infected women.

How does the Latzko Cesarean compare with the Porro operation, in which the uterus is removed supravaginally and free drainage instituted? Table 7 also shows the result in 242 Porro operations taken from the literature. There were 22 deaths, or 9.1 per cent, which is over twice the mortality of the extraperitoneal operation. We have performed 21 Porro operations with 3 deaths, two from hemorrhage, and one from peritonitis, a maternal mortality of 14.3 per cent.

A word should be said about the technical difficulty of the Latzko operation, which is considerable. Extraperitoneal entry must be affected into the lower uterine segment behind the bladder, which must be displaced to the

Table 7
THE EXTRAPERITONEAL VERSUS THE PORRO OPERATION

Extraperitoneal				Porro			
Author	*Cases*	*Deaths*	*Per cent*	*Author*	*Cases*	*Deaths*	*Per Cent*
Burns (31)	79	2	2.5	Seely (7)	11	1	9.0
Sackett (18)	51	4	7.8	Daily (6)	30	0	0.0
Perrins (32)	22	0	0.0	Phaneuf (36)	25	0	0.0
Holtermann (33)	194	10	5.2	Maxwell (2)	11	2	18.1
Norton (34)	26	0	0.0	Lull (17)	10	4	40.0
Fleischer & Keeshner (35)	19	0	0.0	Lash & Cummings (37)	53	6	11.3
				Montgomery (9)	15	3	20.0
	391	16	4.0	Greenhill (27)	9	0	0.0
				Lazard (38)	51	4	7.8
				Arnot (20)	10	2	20.0
Boston Lying-In Hospital 1931-1936	23	0	0.0	Seely (39)	17	0	0.0
					242	22	9.1
				Boston Lying-In Hospital 1931-1936	21	3	14.3

right for this purpose. Unless one is sure of his perivescial geography, he will be confused by the various thin layers of fascia which envelope the bladder and will lose his way. This organ has been torn more than once. In most cases the left ureter is exposed and may be injured. This is no operation for even the boldest general surgeon, nor in fact, for any one who has not received adequate personal instruction at the hands of an expert. Fortunately, there are several accomplished operators in Connecticut who are skilled in the performance of the Latzko operation and who have reported successful series of cases.

Fetal Mortality in Cesarean Section

One would hope that an operation which, generally speaking, carries a maternal death rate of almost 6 per cent would offer as a reward almost a 100 per cent promise of obtaining a living baby. A review of the literature shows that of 3,037 viable infants delivered by Cesarean section 257 died, a fetal mortality of 8.5 per cent. The fetal death rate at the Boston Lying-In Hospital in Cesarean section was 8.8 per cent, while the total fetal mortality in all types of deliveries, both stillbirths and neonatal deaths was only 4.1 per cent.

Table 8
THE FETAL MORTALITY IN CESEAREAN SECTION

Author	*Cases*	*Deaths*	*Per cent*
Boston Lying-In Hospital, 1931-1936			
Stein (13)	385	19	4.93
Phaneuf (26)	169	8	4.7
Adams (11)	217	22	10.1
Seely (39)	135	10	7.4
Seely (7)	203	26	12.8
Palmer (16)	161	16	9.9
Lull (17)	576	74	12.8
Waters & Leavitt (15)	177	21	11.8
Daily (6)	500	31	6.2
Maxwell (2)	296	17	5.8
Schwarz (22)	218	13	6.0
Totals	3,037	257	8.5
Boston Lying-In Hospital 1931-1936	585	52	8.8
Fetal Mortality for all Hospital Deliveries			
Boston Lying-In Hospital 1931-1936	13,688	662	4.8

Surely something is wrong with a method of delivery which is accompanied by a risk of one chance in 11 or 12 of losing the baby, and in our clinic at least, doubles the general fetal death rate. If the operation is done to save the baby, it seems on occasions to be most unsuccessful.

Table 9 shows that the three chief causes of infant death in Cesarean sections are prematurity, atelectasis, and cerebral injury. The 3 leading contributory causes of death are the test of labor, maternal heart disease, and placenta previa. An improvement is possible as regards infant mortality if elective Cesarean sections are postponed until after the 36th week of pregnancy. Since the test of labor was a factor in about one-fourth of our fetal deaths, it is evident that better results may be obtained if trial labors are restricted to from 8 to 10 hours. Too often in the past they have been endurance contests in which the mother, the baby and the obstetrician all took part.

How Does Cesarean Section Compare With Pelvic Delivery as Regards Maternal and Fetal Mortality

Table 10 shows the comparative gross maternal mortality according to various methods of delivery during the 6 year period at the Boston Lying-In Hospital. If we select those forms of operative delivery with which Cesarean section usually competes, that is, high forceps, craniotomy, version, breech extraction and mid-forceps, we have a total of 723 such operations with 6 maternal deaths, or 0.8 per cent. Our mortality in Cesarean section was about four times greater. On the other hand, the fetal deaths in these more serious forms of pelvic delivery numbered 184, a rate of 25.4 per cent. Cesarean section, therefore, is about 3 times safer for the infant. In cases where there is a fair choice between pelvic delivery and Cesarean section one should consider well the increased risk to the mother, who is vastly more important than the infant, before one performs an operation which gives the baby an advantage, even though that advantage be threefold. When Cesarean section be performed in large clinics over a period of years with a maternal mortality of less

Table 9
CAUSES OF FETAL DEATH IN CESAREAN SECTION, BOSTON LYING-IN HOSPITAL, 1931-1936

Chief		Contributing					
		Test of Labor	*Placenta Previa*	*Premature Separation*	*Rupture Uterus*	*Maternal Heart D.*	*Maternal Toxemia*
Prematurity	16		5	1		5	1
Atelectasis	14	4	3	1		3	1
Cerebral injury	12	7	1	1		2	
Dead on admission	4		1	2	1		
Erythroblastosis	2						
Bronchopneumonia	1						
Monster	1						
Achondroplasia	1		1				
Con. heart dis.	1	1					
Totals	52	12	11	5	1	10	2

than 1 per cent, it will be time to broaden the indications, but not before. Note also that of the 12,371 women delivered normally or by low forceps only 38 died, a mortality of 0.3 per cent, which speaks well for conservatism. The fetal mortality in this group was 3.5 per cent, or less than half of that in Cesarean section.

Table 10

MATERNAL AND FETAL MORTALITY ACCORDING TO METHOD OF DELIVERY
BOSTON LYING-IN HOSPITAL, 1931-1936

	Maternal			Fetal	
Delivery	*Cases*	*Deaths*	*P.C.*	*Deaths*	*P.C.*
Cesarean Sect.	584	18	3.1	52	8.8
Craniotomy	16	0	0.0	16	100.0
High forceps	9	0	0.0	4	44.4
Version	106	1	0.9	30	28.3
Breech ext.	493	4	0.8	122	24.5
Mid forceps	90	1	1.0	12	12.0
Low forceps	3,020	14	0.5	78	2.6
Normal	9,351	21	0.2	348	3.7

Indications

In Table 11 appear the indications for our 584 Cesarean sections. While mistakes in judgment have undoubtedly been made, I do not believe that any of our indications are obviously indefensible. It will be noted that 84, or about 1 in every 11 operations were done because of a previous Cesarean section. When the previous Cesarean has been performed in our Hospital for a temporary indication, such as placenta previa, inertia, or disproportion, and the convalescence has been afebrile, we are disposed to allow the patient to go through labor under careful supervision. On a number of occasions we have been rewarded by a simple pelvic delivery. On the other hand, when the operation has been done in another hospital, we usually repeat the Cesarean because we do not have direct information concerning the patient's convalescence. Our present belief is that if the operation has been well performed and there has been no infection the uterine scar may be expected to stand the stress of an ordinary labor.

The indications for hemorrhage need no explanation. It should be said that we attempt to limit the operation in placenta previa and premature separation of the placenta to cases in which the child is living and within the last month of gestation, since we believe that under other circumstances equally good or better results for the mother may be obtained by more conservative measures.

Among other indications will be noted preeclampsia, which was the reason for the operation in 63 cases, and rheumatic heart disease, which accounted for 42. We are attempting to limit Cesarean section in preeclampsia to cases in which the cervix is not suitable for undiction of labor by rupture of the membranes, or where some other complicating factor holds, such as cephalo-pelvic disproportion or elderly primiparity. We have also found that medical treatment is more effective in bringing a cardiac patient safely through her pregnancy than is a surgical delivery. Most women with heart disease, if kept in bed during the last two or three months of their pregnancy, may apparently be delivered through the pelvis with as great safety as by Cesarean section.

Conclusions

1. Cesarean section contributes too large a proportion of all deaths in the puerperal state.

2. Cesarean section in the United States is accompanied by a 5.8 per cent mortality.

3. This mortality is higher than that reported for certain other surgical operations of equal gravity.

4. The lower segment operation is safer than the classical.

Table 11

INDICATIONS FOR CESAREAN SECTION, BOSTON LYING-IN HOSPITAL, 1931-1936

1. Dystocia		*2. Hemorrhage*		*3. Other Indications*	
Contracted pelvis	113	Placenta previa	66	Preeclampsia	63
Previous Cesarean	84	Prem. separation	34	Rheum. heart d.	42
Disproportion	60	Ruptured uterus	5	Eclampsia	2
Inertia	54			Ch. nephritis	2
Transverse	14	Total	105	Diabetes	2
Fetal distress	7	17.9 P.C.		Cong. heart d.	1
Fibroids	5			Hypertensive d.	1
Prolapsed cord	5			Volvulus	1
Breech	4			Resp. obstruction	1
Repaired genital fistulae	4			(spinal anes.)	
Elderly primpiparity	3				
Ovarian cyst	3			Total	115
Previous stillbirths	2			19.0 P.C.	
Contraction ring	2				
Face	2				
Elephantiasis	1				
Compound	1				
Double cervix and vagina	1				
Total	364				

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5. The lower segment operation is not sufficiently safe to be employed in potentially infected cases or those subjected to a prolonged test of labor.

6. For such cases the extreperitoneal operation offers the best prognosis for the mother.

7. The extraperitoneal operation is safer for the mother than the Porro operation.

8. The fetal mortality of Cesarean section in the United States is 8.5 per cent.

9. In electing Cesarean section for the benefit of the infant, it should be remembered that the maternal mortality is considerably increased over any form of pelvic delivery.

10. All indications for Cesarean section should be subjected to the most searching scrutiny.

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From the November 1936 issue of the *Journal,* an editorial by Stanley B. Weld, M.D., Editor:

The American Board of Internal Medicine

With the rapid development of the specialties and the importance assumed by the special fields the American Medical Association has been forced to take action. The House of Delegates has authorized the Council on Medical Education and Hospitals to approve special boards for special examinations in special fields of the practice of medicine. The American Medical Directory has adopted the policy of inserting in the data of physicians listed therein, the possession of certificates issued by these boards. The action thus taken does not bear the unanimous approval of the profession in this country, but with a glance well into the future it would seem to most of us in this section to be a wise step in the right direction. From the far southwest comes the cry that the right to practice medicine should be a blanket right, covering the whole field, and that specialization should be by common consent and concensus of opinion of referring physicians. Our friends in Texas know of people who go directly to specialists as they do in Connecticut and they also recognize the complicated status of the specialty field today, whereby referring physicians are unable to keep up with it.

There has been an insistent demand that the practice of specialties in medicine be restricted to those physicians who are able to demonstrate special training and capabilities in the branch of medicine indicated as their specialty. Already six special boards are in existence and now a seventh is added, the American Board of Internal

Medicine. The restriction thus set up by these boards was intended primarily to safeguard the public, but the movement demanding certification has originated in and been developed by those physicians who would themselves be subject to such examination and certification.

The American Board of Internal Medicine incorporated February 28, 1936 and completed its organization June 15, 1936 by selecting the following officers: Walter L. Bierring, M.D., Des Moines, Iowa, Chairman; Jonathan C. Meakins, M.D., Montreal, Canada, Vice-Chairman; O. H. Perry Pepper, M.D., Philadelphia, Pa., Secretary-Treasurer. The Board comprises in addition to these officers David P. Barr, M.D., St. Louis, Mo.; Reginald Fitz, M.D., Boston, Mass.; Ernest E. Irons, M.D., Chicago, Ill.; William S. Middleton, M.D., Madison, Wis.; John H. Musser, M.D., New Orleans, La.; and G. Gill Richards, M.D., Salt Lake City, Utah. Each member shall serve three years and no member may serve more than two consecutive terms.

The organization of the Board is the result of effective effort on the part of the American College of Physicians in conjunction with the Section on Practice of Medicine of the American Medical Association and these two organizations are represented in the membership of the Board on a five to four ratio respectively.

The American Board of Internal Medicine had previously received the official approval of the two bodies fostering its organization, as well as that of the Advisory Board for Medical Specialties and the Council on Medical Education and Hospitals of the American Medical Association.

The purpose of the Board will be the certification of specialists in the field of internal medicine, and the establishment of qualifications with the required examination procedure for such certification.

While the Board is at present chiefly concerned with the qualification and procedure for certification in the general field of internal medicine, it is intended to inaugurate immediately after July 1, 1937 similar qualification and procedure for additional certification in certain of the more restricted and specialized branches of internal medicine, as gastroenterology, cardiology, metabolic diseases, tuberculosis, allergic diseases, etc. Such special certification will be considered only for candidates who have passed at least the written examination required for certification in general internal medicine. The operation of such a plan will require the active participation and cooperation of recognized representatives from each of such special fields of medicine.

Each applicant for admission to the examination in internal medicine will be required to meet the following standards:

General Qualifications

1. Satisfactory moral and ethical standing in the profession.

2. Membership in the American Medical Association or, by courtesy, membership in such Canadian or other medical societies as are recognized for this purpose by the Council on Medical Education and Hospitals of the American Medical Association. Except as here provided, membership in other societies will not be required.

Professional Standing

1. Graduation from a medical school of the United States or Canada recognized by the Council on Medical Education and Hospitals of the American Medical Association.

2. Completion of an interneship of not less than one year in a hospital approved by the same council.

3. In the case of an applicant whose training has been received outside of the United States and Canada, his credentials must be satisfactory to the Advisory Board for Medical Specialties and the Council on Medical Education and Hospitals of the American Medical Association.

Special Training

1. Five years must elapse after completion of a year's interneship in a hospital approved for interne training before the candidate is eligible for examination.

2. Three years of this period must be devoted to special training in internal medicine. This requirement should include a period of at least several months of graduate work under proper supervision in anatomy, physiology, biochemistry, pathology, bacteriology, or pharmacology, particularly as related to the practice of internal medicine.

This work may be carried on in any domestic or foreign medical school or laboratory recognized by the Council on Medical Education and Hospitals of the American Medical Association as offering appropriate facilities for this type of postgraduate experience; or it may include a period of at least several months of graduate work under proper supervision in internal medicine or in its restricted and specialized branches in any domestic or foreign hospital, clinic, or dispensary, recognized by the above Council as offering appropriate facilities for this type of postgraduate experience.

3. A period of not less than two years of special practice in the field of internal medicine or in its more restricted and specialized branches.

The American Board of Internal Medicine does not propose to establish fixed rules for the preliminary training of candidates for certification in this field. Broad general principles for training, however, may be outlined, although such suggestions as are made must, of necessity, be subject to constant changes reflecting the dynamic nature of the specialty.

A sound knowledge of physiology, biochemistry, pharmacology, anatomy, bacteriology, and pathology, in so far as they apply to disease is regarded as essential for continued progress of the individual who practices internal medicine. The mere factual knowledge of medicine and its basic sciences is not sufficient. The candidate must have had training in their use in furthering his understanding of clinical medicine. This implies practical experience under the guidance of older men who bring to their clinical problems ripe knowledge and critical judgment. Preparation to meet this requirement adequately may be even more difficult to obtain than the so-called scientific training. It may, however, be acquired in the following ways:

(a) By work in a well-organized hospital outdoor clinic conducted by competent physicians.

(b) By a prolonged period of resident hospital appointments likewise directed by skilled physicians.

(c) By a period of training in intimate association with a well-trained and critical physician who has taken the trouble to teach and guide his assistant rather than to require him only to carry out the minor drudgery of a busy practice.

4. The Board does not consider it to the best interests of internal medicine in this country that rigid rules as to where or how the training outlined above is to be obtained. Medical teaching and knowledge are international. The opportunities of all prospective candidates are not the same. Some may have the opportunity of widening their knowledge by a period of study abroad. Others, at the other extreme, may be restricted to a comparatively narrow geographic area and their detailed training must be obtained in short periods scattered over a long time. Although it is laid down that at least five years must elapse between the termination of the first interne year and the time when the candidate is eligible to take the examination, a longer period is advisable. The Board wishes to emphasize that the time and training are but means to the end of acquiring a broadness and depth of knowledge of internal medicine which the candidate must demonstrate to the Board in order to justify it in certifying that he is competent to practice internal medicine as a specialty. The responsibility of acquiring the knowledge as best he may rests with the candidate, while the responsibility of maintaining the standard of knowledge required for certification devolves on the Board.

Method of Examination

The examination required for candidates for certification as specialists in Internal Medicine will comprise, Part I (written) and Part II (practical or clinical).

Part I. The written examination is to be held simultaneously in different sections of the United States and Canada and will include:

(a) Questions in applied physiology, physiological chemistry, pathology, pharmacology, and the cultural aspects of medicine.

(b) Questions in general internal medicine.

The first written examination will be held in December 1936, and candidates successful in this written test will be eligible for the first practical or clinical examination which will be conducted by members of the Board near the time for the annual session of the American College of Physicians at St. Louis in April 1937. The second practical examination will be held at Philadelphia near the time of the annual session of the American Medical Association in Atlantic City in June 1937.

The fee for examination is forty dollars which must accompany the application and an additional fee of ten dollars is required when the certificate is issued.

Application blanks and further information can be obtained by addressing the office of the chairman, Walter L. Bierring, M.M., 406 Sixth Avenue, Des Moines, Iowa.

Freedom and Security

When a man's property rights are protected, he is able to retain and enjoy in peace the fruits of his labor. This security is his main incentive, if not his only incentive, to labor creatively. If anyone were free to confiscate what the farmer had sown, fertilized, cultivated and raised, he would no longer have any incentive to sow or to reap.

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It is said at times that many are willing to trade freedom for security. Even if they were to receive that for which they traded, it would be a bad bargain. But the sad and frightening fact is that when a people seek to obtain security by turning over power and responsibility to government, they lose both freedom and security.

—Ed Grady, *The Freeman*, August 1986

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From the June 1942 issue of the *Journal:*

The Centennial Meeting of the Connecticut Medical Society

CHARLES J. FOOTE, *New Haven*

The year 1892 was memorable, not only for the hundredth anniversary of the Connecticut Medical Society but for notable advances in medicine. Among these may be mentioned the introduction of the use of rubber gloves in operative surgery by Halsted of Johns Hopkins, and the directing of public attention to fly control in the prevention of typhoid, by Sedgwick of the Institute of Technology in Boston. However, the year belonged to "the horse and buggy" era for there were no automobiles and no trolley cars.

The members of the Connecticut Medical Society who would attend the annual convention for 1892, came via rail-road to New Haven station. They would then take an infrequent horse car, or else walk to the corner of Church and Chapel Streets. On their way they would see on the south east corner of George and Meadow Streets an old stone house built and occupied a hundred years before by Dr. Leverett Hubbard, the first president of the Connecticut Medical Society. Fallen from its high estate at that time it was used as a beer saloon.

As the members approached the corner of Church and Chapel Streets, they would notice a town pump on the corner of the green, and attached to it by a chain was a large pewter cup, out of which the community drank with no restriction of class or type of disease, whether tuberculous, syphilitic, or diphtheritic. The water came from a shallow well filled by the surface drainage from the immediate vicinity. The members would stop to admire the fine old elms on the green with their luxuriant foliage, not then devastated by the elm tree beetle, and to look at the velvety greensward. As they approached the college, they would see another pump, the college pump, where for a hundred years or more the students quenched their thirst and at an earlier period performed their morning ablutions. Studying the city more carefully, they would find many streets of the city without sewers, and numerous cesspools often not far from wells used for drinking water.

Looking over the health records they would find New Haven a fairly healthy city, according to the standards at that time, having a lower death rate than most cities of its size, yet they would find that there were twenty-five to thirty deaths annually from typhoid fever, indicating a morbidity of perhaps a hundred or more cases every year. In the State for the year 1891 there were 312 deaths from typhoid, 435 from diphtheria and 67 from scarlet fever. If the visiting member should consult any of the local physicians he would find that there were nearly always ten to a dozen cases of typhoid in the New Haven Hospital every autumn, placed in the same ward with cases of pulmonary tuberculosis. All of these conditions of necessity tinged the subjects of discussion at the medical convention. However as it was an anniversary year, many of the papers presented at the Centennial related to the past.

The meetings of the Society's Centennial were held in Dwight Hall, the Yale Y.M.C.A. building, a fine stone building on the old campus between the Wright dormitory and the old library. The building was torn down some years ago. It had a fine auditorium for the general meeting, and smaller rooms for the various sections.

To understand these meetings and this period from the medical viewpoint one must think of treating disease without most of the laboratory helps and remedies that we now think essential. There was no diphtheria antitoxin then, and in spite of the prevalence of the disease, there was no contagious disease hospital. The only thing of the kind was shack at Springside, called the pest house and used for cases of small pox. There were no tuberculosis sanitaria and patients in the last stages of pulmonary tuberculosis were placed in the same wards of the general hospital with patients with other diseases. There was no insulin and no liver treatment for pernicious anaemia. Deficiency diseases were not recognized and vitamines were unknown. X-rays were not dreamed of. Antiseptic surgery was just coming into its own in this country, with Lister dressings and the use of carbolic acid for cleansing the hands and the field of operation. The carbolic spray had just been discarded.

Yet the physicians in this year 1892, glorified in the progress that had been made since 1792. The chief emphasis was placed on the discovery of anaesthesia which was naturally attributed to Horace Wells of Hartford. In looking over the programme of the meetings we find that about fourteen papers were devoted to historical subjects, such as "The Alcoholic Question One Hundred Years Ago and Today," "History of Empiricism in the Past Century," "History of Therapeutics in the Past Century," etc.

There were some outstanding addresses on historical subjects. One of them was by Dr. Gurdon Russell of Hartford on "Early Physicians, and 'ye State of Medicine in Connecticut Previous to 1792". This was a most exhaustive and schorlarly document filling one hundred and forty-five pages of the transactions of the society, and must have been somewhat abridged in the reading. It was a paper invaluable for reference for any one studying the early history of medicine in Connecticut. Much of the information unearthed by Dr. Russell is from court records and relates to litigation and the collection of debts. In some instances it does not leave an heroic impression of the doctors of colonial times. But it would be ungracious to judge them by these records. Would we at this time fare any better if our own biographies were largely limited to court records? To get a true idea of the colonial doctor we must read between the lines. We know that in the care of the sick he traveled many miles on horseback through trails in the woods infested with wolves and indians, often through snow and rain; that he had a most pitiful pharmacopeia which he made with his own hands, collecting native herbs and roots. He must have been an expert botanist and have known quite well the physiological effect of many of his remedies.

Another paper was by Dr. Francis Bacon of New Haven, on "The History of the Connecticut Medical Society." This paper is equally valuable to one studying the past history of the society. It is a very interesting paper, interspersed with humor and apt quotation with a fine vein of sarcasm running through parts of it. Dr. Bacon at that time was recognized as the foremost surgeon in the state. He was a man most cultured, with a broad knowledge, a fine command of the English language, gifted in speech and courtly in manners. Other papers of considerable interest were one by Mr. Charles J. Hoadley on "Some Early Post Mortem Examinations in New England" and one by Dr. C.A. Lindsley on "The Beginning and Growth of Sanitary Legislation in Connecticut". Most of the other papers were read before the sections. Of these perhaps the ones that were most discussed were those on intubation of the larynx, and anaesthesia.

One cannot pass from this subject without reference to two interesting papers that are worth re-reading, a paper by Dr. Rufus W. Griswold of Rocky Hill on "The Materia Medica and Therapeutics of a Hundred Years Ago" and one by Dr. Miner C. Hazen of Haddam on "The Centennial History of the Middlesex County Medical Association." The year 1892 was a time of disillusionment regarding the treatment of tuberculosis with Koch's tuberculin. There is only one reference to it in the proceedings, in a paper by Dr. C.H. Newton of Stafford Springs, in which he gave a summary of the remedies used at that time in the treatment of tuberculosis.

Altogether the transactions of the society for 1892 present an interesting volume and one might say of them as Carlisle wrote of another book, "An extensive volume of boundless almost formless contents, a very sea of thought; neither calm nor clear." There was naturally some discussion of typhoid fever by the society. One paper was read on the prophylaxis of typhoid, that excited some discussion. I remember that a charming old doctor from back on the Connecticut Hills wanted to know where the first case of typhoid originated and why the disease might not arise again in the same way. One member thought that the typhoid bacillus was either the result of a special act of creation like Adam, or else was the product of evolution. He rather placed himself in the unregenerate class and regarded the bacillus as the product of evolution. In either case he thought the process was not likely to be repeated.

Some weeks before the meeting of the society Dr. Herbert Smith, Dean of the Yale Medical School, came to the writer and told him that Dr. Moses White was going to have an exhibit of pathological specimens and photomicrographs in the Yale Medical building on York Street. He suggested a bacteriological exhibit as part of it. He wanted the bacteriological laboratory of the Yale Medical School put on the map, and the physicians of the state to know that it was a live part of the school. It devolved upon the write to prepare most of the cultures and the stained micrscopic specimens. We made cultures in gelatine and agar, and sera of various bacteria. Among them were cultures of the B. tuberculosis, B typhosus, B. coli, B. anthrax, Klebs Löffler bacillus, spirillum of Asiatic cholera, staphlococcus albus and aurens, as well as many water bacteria, and to add color to the exhibit some chromogenic bacteria such as B. prodigiosus, B. violaceous and the yellow sarcina. Smears were made from each culture and stained and placed under a microscope near the culture. They were all plainly labeled.

These made quite a display and attracted much attention and either Dr. Smith or the writer was there much of the time to demonstrate the specimens.

There were several incidents in the meeting that should be mentioned. Sir Joseph Lister was made an honorary member of the society. This was the year that he was to receive a great ovation at the Pasteur Jubilee in Paris. He came to this country in 1876 and delivered an address on the antiseptic treatment of wounds to the physicians of Philadelphia but it aroused little interest and it was six or eight years later before the eyes of the surgeons here were opened to the cause of infection.

Another interesting incident was the visit of Dr. James R. Chadwick of Boston, who brought with him letters of the first practitioner of the State of Connecticut, John Winthrop, Jr. There were twenty-two other letters addressed to Mr. Winthrop, asking advice in cases of sickness. These letters with a portrait of Governor Winthrop were carefully bound and furnished an interesting and valuable souvenir of the historic occasion.

Dr. J.B. Lewis of Hartford prepared a list of members of the Society since its foundation. The number was 2700. At that date the membership was 524. The physicians of New Haven and the New Haven Medical Association were most hospitable during the meetings, and vied with each other in furnishing entertainment for the visitors. Doctors Carmalt, Lindsley and Whittemore gave fine luncheons at their homes and in the afternoon the New Haven Medical Association furnished transportation tot he top of East Rock to all who wanted a breathing spell and rest from the strenuous meetings. The annual dinner was held in Warmer Hall. This was quite an elaborate affair. Dr. Francis Bacon was toastmaster and among the speakers at the dinner were Prof. William H. Welch, President Timothy Dwight, Rev. Newman Smyth, Dr. George S. Porter and Mr. Norris Osborne. Included among the guests were Dr. Henry O. Marcy, Prof. R.H. Fitz of Harvard, and Dr. E.G. Janeway of New York. I remember only two of the after dinner speeches, one by the Rev. Newman Smyth, in which he spoke most appreciatively of the bacteriological exhibit; the other was by Dr. George L. Porter of Bridgeport who recited a humorous poem on eight day clocks.

This dinner closed the one hundredth anniversary of the Society. Will there be as much progress in the next fity years as there has been since 1892? The outlook is hopeful. "The torch still burns—perhaps more fiercely than ever—so that not the smallest cranny or dog hole in nature or art can remain unilluminated."

Daniel C. Patterson, M.D., Bridgeport, was the Society's delegate to the Thirty-Second Annual Congress on Medical Education, Medical Licensure, and Hospitals, 1936. A portion of his report follows:

Mr. President and Gentlemen of The House of Delegates:

The Thirty-Second Annual Congress on Medical Education, Medical Licensure and Hospitals was held in Chicago on February 17th and 18th, 1936. In spite of considerable snow and subzero weather there was a large attendance.

In the section on Medical Education the speakers laid stress on the necessity of culture and understanding on the part of the physician, as well as the knowledge of his profession, and that we should be more concerned with the quality of medical graduates, than quantity. Some speakers were of the opinion that the number of graduates should be further restricted, while others saw no danger of over-production, pointing out that the capacity of society to absorb well-trained physicians was unknown.

Emphasis was placed on the need of teachers with enthusiasm and initiative, and the importance of a student being informed of his social obligations, and it was suggested that this should be a part of his premedical education.

Doctor Cutter reported on the survey of medical schools and said that the investigators had met with great courtesy and cooperation on the part of the schools; that the work had progressed steadily and it was expected that much good would come from it. He pointed out that it was not the function of the survey to curtail the number of students in any way. He felt that in some cases the number of students admitted to certain schools had greatly exceeded the capacity of the medical equipment, and that increase in the student body should not be made without corresponding increase in equipment. He felt that better methods for evaluating the graduate must be devised.

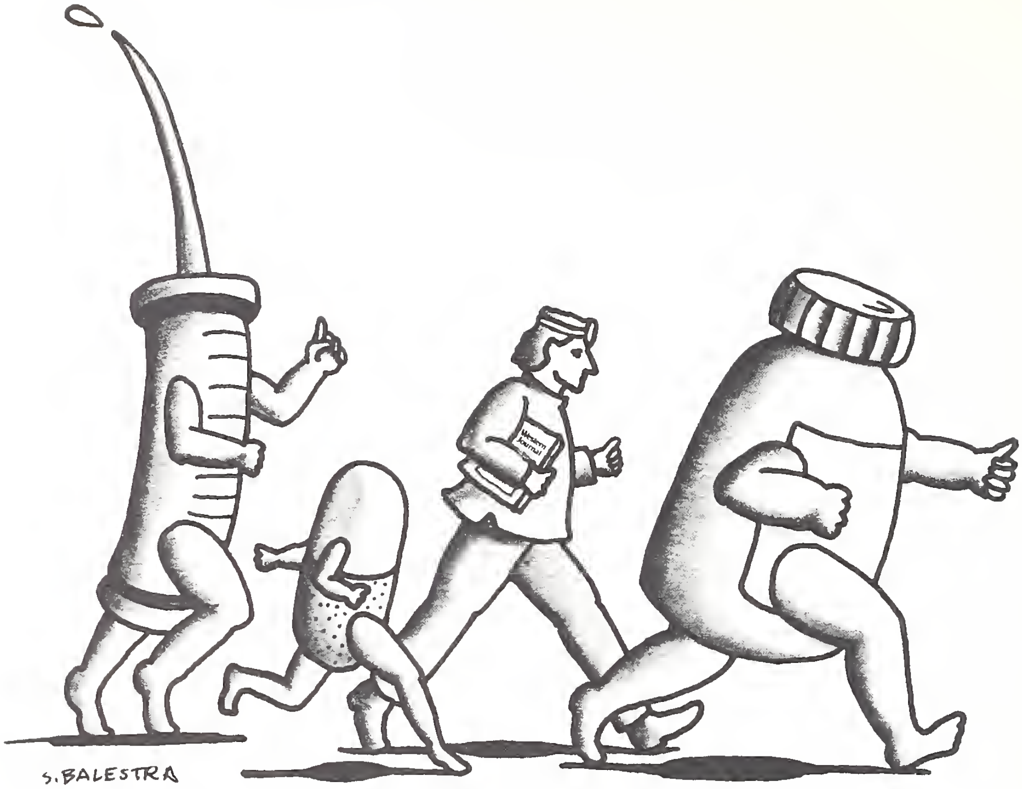
President Metzger's Presidential address was on the "Art of Medicine." He felt that the old preceptor system had an advantage in that a young man entering the profession had an opportunity to see what he was getting into, while today a student is well along in his course before he comes in contact with sick people, and at that time may find that he is miscast. He remarked that medical knowledge in itself does not insure success. The Art of Medicine requires that the physician enter into the lives of his patients. He pointed out that there was a difference between knowledge and wisdom. He thought the time was coming when examining Boards would lay less stress on scientific knowledge and much more on the mental, moral and social adaptability of the applicant. To quote: "All recognized medical schools furnish ample scientific training to assure reasonable service to the sick", and he thinks that we should examine their mental fitness, and then possibly give them a provisional license for five years. At the end of that time they should be re-examined for a permanent license.

Several protests were made against the elimination of two-year schools, but as the committee had already changed its decision not to recognize these schools after 1938, the question is at rest for the present.

There are ten such schools, namely, Dartmouth; W. Va.; N.C.; Wake Forest; Ala.; Miss.; S.D.; N.D.; Utah, and Mo. The proponents point out, among other advantages, that most of their students returned to their native state to practice, and if this source of supply is shut off there would be a real shortage of doctors in those communities.

Respectfully submitted,
D.C. Patterson

—*The Journal,* August 1936



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From the January 1976 issue of *Connecticut Medicine*
(Dr. Weld was at that time Editor Emeritus):

A Journey into the Past: History of the *Connecticut State Medical Journal* 1936 – 1958

STANLEY B. WELD, A.B., M.D.

As the Connecticut State Medical Society moved into the 1930's the work of the part-time Secretary, Charles W. Comfort, Jr., steadily increased. The annual volume of Proceedings of the Society was appearing about one year after the period covered. It was apparent to many that this situation was producing problems in keeping the membership informed of the activities of the Society's officers and Council. In his report to the House of Delegates as Chairman of the Council, James Douglas Gold, on May 25, 1935, discussed the desire for a more effective business organization in the Society and the fact that there existed "agitation for a full-time secretary and a business office for the Society." The following day the House of Delegates voted to request President Murdock to appoint a "Committee of 8 to inquire into the Administration of the Office of Secretary." This was done and, as a result, at a meeting of the House of Delegates convened in New Haven on January 16, 1936, the Council made the following recommendations: (1) that the single annual volume of the Proceedings be discontinued; (2) that in place of the Proceedings a Quarterly Bulletin of the Society be published in May, August, November and February of each year and distributed to all members of the Society, listing what the Bulletin should contain; (3) that there be created the office of Administrative Secretary chosen from the Society membership, also a Legislative Secretary, and a Secretary on Scientific Work. At the next session of the House held in Hartford on May 21, 1936, their recommendations were approved and the following were elected: Creighton Barker, then serving as Secretary of the New Haven County Medical Association, to be Administrative Secretary; Charles W. Comfort, Jr., to be Legislative Secretary; and Stanley B. Weld, then serving as Secretary of the Hartford County Medical Association, to be Secretary on Scientific Work and Editor of the Bulletin. In the annual budget for that year $1,400 was allocated for publication of the Bulletin. It was also voted to establish an office for the Society, this to be in charge of the Administrative Secretary. The Editor of the Bulletin was to carry on his duties from his office in Hartford.

The first issue of the Society's new publication appeared in August of 1936. Instead of the Bulletin it was named The Journal of the Connecticut State Medical Society. No official vote for this change of name appears in the records, hence it is to be assumed that the Editor used the prerogative of his office in making the change to conform to the pattern of other state medical journals. That first issue was dedicated to the late James Tate Mason who died while President of the American Medical Association (AMA). The printer was James Reid in Hartford, and all the advertising at first was obtained by the Editor, who took Thursday of each week from his practice to travel the State in the securing of advertising contracts. This initial number of the Journal contained editorials on Medical Expert Testimony and Social Security in Connecticut; messages from Daniel C. Patterson, president of the Society, and James D. Gold, chairman of the Council; a paper on Medical Expert Testimony by the Society's immediate past President, Thomas P. Murdock, and one on Activities of the State Department of Health In Carrying Out Procedures of the Social Security Act by Commissioner Stanley H. Osborn; Proceedings of the House of Delegates for the May 1936 session; program of the Twelfth Clinical Congress, and a list of the officers and committees of the eight County Medical Associations. When the second issue appeared in November 1936, it contained many favorable comments from prominent physicians across the country. At the meeting of the House of Delegates in May 1937, Dr. Barker was very gracious in his remarks regarding the Journal. The paste-up of the dummy for the printer was done by the Editor, usually in his home, and this con-

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DR. STANLEY B. WELD, Fellow of American College of Surgeons, American College of Obstetrics and Gynecology, and American Association for the Advancement of Science. Member of Hartford Hospital Medical and Surgical Staff, Connecticut Historical Society, and Beaumont Medical Club. Historian of Immanuel Congregational Church of Hartford. Secretary, Dartmouth Class of 1912. Past Master of Hartford Lodge of Masonry. Member of local, county, state and national medical societies. Editor of The *Connecticut State Medical Journal* 1936 to 1958.

tinued throughout the entire 22 years. The second issue contained several advertisements of national companies. Soon after the appearance of the first issue the Editor was in touch with the Cooperative Medical Advertising Bureau of the AMA and from that time on the Journal was the recipient of considerable advertising copy through this medium. As the year 1937 progressed, it became evident that in order to receive the maximum of assistance from the Bureau in Chicago the Journal should become a monthly publication rather than a quarterly, hence the change was made beginning with January 1938 and approved by the House of Delegates.

At the session of the House in May 1937, the Council was empowered to appoint an Editorial Board to consist of four members in addition to the Editor-in-Chief as chairman. All the editorial and advertising policies were invested in this Board. The first Board consisted of Herbert Thoms of New Haven for 4 years, Frank S. Jones of Hartford, designated Custodian of Funds, for 3 years, Oliver L. Stringfield of Stamford for 2 years, and Charles Mirabile of Hartford for 1 year. The Treasurer of the Society was instructed to pay the Custodian of Journal Funds $1.25 per capita annually as a subscription charge for the Society's membership. With this sum and the income from advertising the Journal was expected to carry on. The Editor-in-Chief, now named as such, was receiving a modest stipend for his services.

In September 1938, the duties of the Secretary on Scientific Work were divided by the creation of a Program Committee and a Journal Editor. This was a welcome move for the Editor-in-Chief, who found the Journal as a monthly publication sufficiently time-consuming.

Gradually the relationship established with the Cooperative Medical Advertising Bureau, a national organization, became one of deep and lasting friendship. The Bureau held a very instructive two-day session each year, known as the Conference of Secretaries and Editors, to which each State journal editor whose publication was a member became an invited guest without any registration fee. The Connecticut Journal was well represented at these sessions and its Editor was often a participant in the program. It was not long before he became Chairman of the Medical Advisory Committee of the Advertising Bureau and continued in this capacity for many years. Within his term of office the Medical Advisory Committee found itself at odds with the Trustees of the AMA to the point where it was felt advisable to terminate this relationship. This was done, not without some rancor on the part of certain AMA officials, but it proved very satisfactory and productive. The name of the Advertising Bureau was changed to State Journal Advertising Bureau.

One of the first members of the Editorial Board to submit a paper for publication was Frank S. Jones, whose subject was "The Use of the Rogers Method in Treating Uncomplicated Compression Fractures of the Spine." This appeared in February 1937. Beginning in August of the same year several designated sections appeared in addition to the scientific papers. These included Association of Connecticut Tumor Clinics; State Department of Health; American Public Health Association; The President's Message; From the Secretary's Office; News from County Associations; President's Proscenium (for those of other State Societies); Our Neighbors; Editorials and Abstracts from other journals, and Book Reviews, later called Quarto Notes. There was an occasional section devoted to the Institute of Living, one for Orthopedic Surgery, and a list of placement opportunities for Connecticut physicians. The Roster of the Society appeared in August each year and the Charter and By-Laws in February. A special feature of the Journal from time to time was the dedication of a particular issue to a certain prominent dignitary such as the Governor of Connecticut or the President of the AMA.

In May 1938, the name of Creighton Barker appeared as both Executive and Legislative Secretary. In September the masthead included the County News Editors, six of the eight with Tolland and Windham added later. As provided by direction of the House of Delegates, its proceedings were published in detail, as well as the papers delivered at the Clinical Congress. That year many interesting articles, in light of present day experience, dealt with lung and heart surgery, advances in anesthesia, drug and alcohol problems and an amazing number on syphilis. The editorials for the most part were written by the Executive Secretary and the Editor and were not signed.

In October 1938, the Journal set up a separate office at 54 Church Street in Hartford and placed in charge a full-time stenographer "of experience." The Journal Board was meeting quarterly in New Haven.

The year 1939 was a busy one for the Journal. Advertising increased 30 per cent over the previous year. The Connecticut Bar Journal reported an article on Physicians and Lawyers by Attorney George H. Cohen. In March appeared an editorial on the problems of assimilating the refugee physician, and new sections on The Doctor's Office and on Proctology were added. Two months later began the first of a series of articles on the proper selection of accident and health insurance and of life insurance. Prepayment Medical Care and Federal Health Insurance were lively issues under discussion, and in August the subject of Birth Control made its debut in a paper from Waterbury. The December issue carried the Journal's first historical article, "Litchfield County Medical Association and Dr. Elias Pratt" by Walter R. Steiner. At the House of Delegates meeting in May 1939, Dr. Barker was made a full-time Executive Secretary, effective January 1940. The annual dues of the Society were increased to $15.00 and the Society budget for the Journal set at $2,400. A committee was appointed by the president to study the status of the osteopathic physician. Those members of the Society of over 40 years standing were exempted from dues at this time. This became a regular provision in subsequent years.

The Connecticut Hospital Association made a formal request to be allowed to use the Journal as its official publication. This was approved and made effective with the issue of January 1940, in which a section was allocated to it, and Sidney G. Davidson was made its representative on the Journal Board. A General Practitioner's Forum, subsequently called The Forum, was added to the Journal for the discussion of the latest developments in medicine, and a representative from the Yale School of Medicine, Arthur J. Geiger, was added to the list of County News Editors. Prepaid medical care was evoking interest as evidenced by the fact that the House of Delegates in May voted to request the President of the Society to appoint a Committee of 5 to investigate this matter. The clouds of war appeared to be getting darker and closer. Medical Preparedness For War attracted the interest of the Society, and the AMA held a national conference on this subject in Chicago. Several articles on this subject were published in the October 1940 issue together with an accompanying editorial. The following January this became a regular section of the Journal. Near the end of 1940, a second historical article appeared, this time "The Beginning of Medical Practice in the New Haven Colony" by Herbert Thoms. Under his leadership a series of such articles followed, leading up to Society's Sesquicentennial in May 1942.

A principal innovation in 1940 was the selection by the Board of a local advertising representative to operate on a commission basis. That same year the by-laws of the Society were amended to make the Editor a member of the Council. The financial success of the Journal in 1940 enabled the Society to realize an ample operating surplus. The budget for the Journal now stood at $3,600.

When the March 1941 issue appeared in a new cover with a border of Colonial red designed by Dr. Thoms, some unwary individuals mistook it for TIME magazine. There were several other changes, notably a new format and new type, for a change had been made to a new printer, the Whaples-Bullis Company in New Haven. The representative of this company, Donald P. Bullis, a graduate of Rensselaer Polytechnic, proved of great assistance to the Editor in the following years. A Legislative Section now appeared each month and later in the year a section on Industrial Health and one on Public Affairs were added. Dr. Thoms was appointed Vice Chairman of the Sesquicentennial Committee and Chairman of its Planning Committee, with the Editor a member of the latter.

1942—the U.S. was now in the war following the devastating attack on Pearl Harbor by the Japanese. Secretary Barker, in the columns of the Journal, offered assistance to those physicians applying for commissions in the Medical Corps of the Army or the Navy. Each month appeared an increasing number of articles relating to physician activities in, and the problems of, World War II. A section, Medicine and the War, was started and a special correspondent, Francis A. Sutherland of U.S. General Hospital No. 39, was added to the list of County News Editors. The Editorial Board was meeting almost monthly, and the Editor found himself a member of the Connecticut Procurement and Assignment Service.

This was also the year of the Society's 150th anniversary. Dr. Thoms was compiling a sesquicentennial volume, *The Heritage of Connecticut Medicine*, to be available at a modest price. In this volume were included historical articles by, among others, the two Editors and the Secretary of the Society. The anniversary program took place in Middletown on June 3 and 4, 1942, the same city where the first meeting of the Society was held on October 9, 1792. It was a notable session, well documented in the special Anniversary Number in June which netted the Society a profit of $1,500. In this issue there were greetings from Governor Hurley of Connecticut, the President-Elect and the Chairman of the Board of Trustees of the AMA, President Gold and President-Elect Leak of the State Society, the Presidents of the other State Medical Societies and of the New York State Society, and the five College Presidents in Connecticut. The orator of the day was Professor Logan Clendenning of Kansas and the Anniversary Dinner was addressed by Colonel Fred Rankin, President-Elect of the AMA. Included were many historical items of interest as well as historical articles, two of the latter by the Executive Secretary and the Editor. Photographs were included of officers and committee chairmen.

The House of Delegates, meeting in Hartford in May 1942, elected Herbert Thoms to be Literary Editor and the Editor was then named Editor-in-Chief. Harold S. Burr of New Haven and Lee D. Van Antwerp of Meriden were added to the Editorial Board from which Charles Mirabile retired at the expiration of his term of office. The elevation of Dr. Thoms to Literary Editor proved to be an exceedingly propitious step. He served the Journal for over two decades and did much to stimulate members of the Society to write for publication. He continued his interest in securing and publishing historical articles and by his work enhanced the value of the Journal and helped to place it among the best of its class. From then on for several years the major part of the editorials were written by him.

In September 1942 were published two articles on women in industry in relation to the war. Two months later appeared an outline of the contents of a book to be published, titled *Essentials of Emergency Practice*. This volume was written entirely by members of the State Medical Society and was conceived and produced by Dr. Thoms. The fact that there existed a shortage of nurses was receiving attention and was emphasized by an article in the November issue. The Society's budget for the Journal had now reached $4,000, but in that year it used only one-half of this amount.

The following year, 1943, saw many changes in the Journal, now having reached its seventh birthday and having attained a position as one of the foremost and most attractive of the State medical journals. In June, Paul P. Swett was added to the Board in charge of the large number of exchanges, both national and foreign. He replaced Lee D. Van Antwerp, then serving in the U.S. Army. The Literary Editor was made a member of the Council and was named Secretary of the Committee on Clinical Congress. The Editor-in-Chief was made a member of this latter committee, as well as of the Committee on Prepaid Medical Service, along with Oliver L. Stringfield from the Board. Less frequent meetings of the Board were held that year, probably due to the increasing demands being made on the time of physicians. The State Society in 1943 took a forward step in forming a Woman's Auxiliary, to which was allotted each month a place in the Journal.

The December issue was dedicated to the Connecticut physicians serving in the armed forces and contained 16 pages of letters from this group as well as a list of all those in the service. Letters from this group appeared each month during World War II. A new section, Across the Continent, was added, containing important news from other State medical societies. In addition to historical articles and those relating directly to the War, the issues of 1943 produced some very interesting discussions. There was the Sister Kenny treatment of poliomyelitis victims, the Beveridge Plan for social security in Britain, sulfonamide therapy, a preliminary Report on Prepaid Medical Service with editorial comment, the Wagner-Murray-Dingell bill for social security in the U.S., and the decision of the Society to proceed with a prepayment plan for medical service. The tragic Cocoanut Grove fire in Boston was covered in the February issue. On the lighter side there were monthly comments by Peripateticus, written by anonymous authors.

After the sesquicentennial the idea of a permanent home for the Society was brought up from time to time. A committee to study the matter issued a favorable report, as a result of which the House of Delegates voted in 1944 to proceed with construction of a building. Definite plans were drawn up under the guidance of the Trustees of the Building Fund, with Dr. Gold named as chairman. By mutual consent, the Connecticut Hospital Association was dropped from the Journal in January 1944 and Sidney G. Davidson resigned from the Editorial Board. The Editor-in-Chief was named Chairman of Region 2 Wartime Medical Meetings, which were to provide postgraduate and refresher courses of study to medical officers of the Army and Navy serving at home stations. The problem of professional liability insurance appeared that year and a committee was appointed to make a study of it. The Hartford circus fire struck on July 6, resulting in scores of dead and severely burned. This was covered in the Journal and led at a later date to several timely articles on the treatment of burns. Four special issues appeared that year, the one in December again featuring letters from Connecticut physicians in the Armed Forces, this time numbering a total of 32 pages and including a thrilling account of the escape of Captain Francis Gallo from a German train of prisoners.

During the war years which followed, the Journal continued to flourish. It published important news of Connecticut physicians in the Armed Forces, listing the names of those in the service. Toward the end of the war the names of those returning were published. Many of our doctors received citations and awards for valiant service, and these were prominently noted in the Journal, along with the names of casualties. Advertising continued to increase with the advent of color produced by a new process, to the extent that in 1945, when the Journal was ten years old, it realized a profit of $2,600. The Editorial Board decided to depart from the firm principle of the AMA and to accept advertisements of drugs well proven by usage, but not approved by the Council on Pharmacy and Chemistry. In this the Board was fortunate in having the advice and assistance of Dr. William T. Salter of the Yale School of Medicine. After several confrontations the AMA saw the light and broadened its advertising policy.

Letters from members in the Armed Forces, usually in large numbers, continued in the annual Army and Navy Number. In March 1945, the Navy called for 4,000 more physicians, and the following year the Army announced the need for 60,000 R.N.'s. The Journal made known the fact that a curriculum for intern and residency training had been arranged by the Society's Post-War Planning Board. In 1945 a new section, Medicine and the Veteran, was added and a special Veterans Number was published. In November the experience of one of our members at the bombing of Nagasaki was a special feature. An unusually fine article on "Medicine During World War II" by Dr. Perrin Long of Johns Hopkins appeared in August 1946. That was an outstanding year for the Clinical Congress and was also the Centennial Year of the Hartford Medical Society, written up specially for the Journal. In September 1946, the section on Medicine and the War was eliminated. At this time a special committee was appointed to complete a history of the Society's participation in World War II.

The campaign for funds for the Society's new home contined, with a list of donors published at intervals in an endeavor to reach the goal of $50,000. In 1946 property was purchased at the corner of Edwards and St. Ronan streets in New Haven, and plans were drawn up for construction of a building.

Many duties as well as honors were accorded the two Editors and there were some changes in the Board. The Literary Editor, early in 1946, published a suggested plan to augment graduate medical training. He was elected Vice Chairman of the Clinical Congress and appointed to the Advisory Committee from the Council to the Trustees of the Building Fund. It was due to his close association on the faculty of Yale Medical School that the Journal enjoyed a very happy and profitable relationship with that institution throughout the years. The Editor-in-Chief was elected a delegate to the AMA and was appointed one of two representatives to the New England Post Graduate Assembly. From the Editorial Board, Arthur Geiger was appointed to the Committee on State Blood Bank Donor Services, and Frank S. Jones to the Committee on Health and Physical Education. Lee D. Van Antwerp returned from the war and in May 1946 was re-elected to the Board to replace Oliver L. Stringfield, whose term had expired. Van Antwerp was commissioned lieutenant colonel in the Connecticut national Guard and placed in command of the 118th Medical Battalion. Paul Swett, who had been elected to fill the vacancy on the Board left by Sidney Davidson's resignation, now furnished the Journal with an historical article on "Orthopedic Surgery in Connecticut." This was completed in two issues.

The years 1945 and 1946 were full of the discussion of problems vital to the medical profession. Possibly the hottest subject was that of compulsory health insurance, previously instigated by the Murray-Wagner-Dingell bill and by the example set by the Beveridge Plan in Britain. One of the best presentations of this problem, prepared specially for the Journal, appeared in May 1945 and was written by James R. Miller. That was only the beginning, the end of which is not yet in sight. President Truman made public his own health program, which was but another form of socialized medicine. There were also articles on school health education; medical care, particularly of tuberculosis and the industrial worker; care of the chronically ill; medical care of the veteran, which was finally placed in the hands of the individual States, and prepaid medical service was discussed, for which the AMA had its own plan. The Council appointed a committee to study the operation of the Workmen's Compensation Law. The Hill-Burton Hospital Construction Act, Blue Cross (prepaid hospital insurance), and Group Practice all were mentioned in the Journal. Discussion of a second medical school in Connecticut appeared in November 1946, and two articles introduced the reader to problems of future years, "Early Rising in the Puerperium" and "The Rh Blood Factor." The Society made a change in its by-laws to admit medical students to its membership.

In 1946 the Editor-in-Chief was made Chairman of the State Journal Advertising Bureau. That same year the member journals of the Bureau agreed to return to the use of advertising products approved by the Council on Pharmacy and Chemistry as it had satisfactorily revised its rules. In the December issue the President of the State Medical Society, in his annual address, praised the Journal as one of the best in its group. The section previously called Correspondence was changed to Letters to the Editor in the hope that it would provoke more expressions of opinion from its readers.

At the beginning of 1947 the Journal was continuing to discuss the many problems of medical practice, emphasizing public relations, the care of veterans and the treatment of hypertension. The Literary Editor was co-author of an article on the "Rooming-In Plan for Mothers and Newborns," and there were many articles dealing with cancer, to the extent that a special section was allotted to this field. Medical care continued to hold a prominent place, influenced by the number of bills introduced into Congress. The Editor-in-Chief was the author of "Connecticut and the Founding of the American Medical Association," appropriately timed to coincide with the centennial celebration of the latter.

July 25, 1947 officially marked the end of World War II, but for over a year physicians had been returning from military sevice and were so listed each month in the Journal. A regular feature was News from Washington placed in the section on Public Affairs for the purpose of keeping readers informed of government developments. Early ambulation was not being extended to surgical patients. The shortage of nurses was presenting a problem, added to their demand for shorter hours and more pay. As one method of solution there appeared a discussion of the Practical Nurse. Socialized medicine in Europe was gaining attention. The Hartford Community Cancer Clinic was featured and the State announced its decision to treat subjects of alcoholism as patients, not criminals. Each month there appeared editorials by George Blumer, signed G.B. Dr. Barker supplied biographies, and television had now arrived in the operating room.

At the meeting of the House of Delegates in May 1947 Benjamin V. White was elected to the Editorial Board to replace Lee D. Van Antwerp who had resigned to join G.D. Searle & Co. Dr. White became responsible for the section on Progress in Medicine. The profit of the Journal that year amounted to $2,060. The year ended with a reminder from the Trustees of the Building Fund that memorial gifts were being received but subscriptions were lagging and building costs rising.

At the Secretary-Editors Conference in Chicago in November 1947 the representative of the Waverly Press in Baltimore announced that the Connecticut Journal showed outstanding typographic distinction and was the most legible and attractive of the four State journals selected for consideration. This was very gratifying, as the other three were of top quality.

The year 1948 was an active one for the Journal as well as for the Society. The Committee on the Study of the Organization of the State Medical Society sent out a questionnaire to all members in order to evaluate reader interest in the Journal. Of the one-third replies, 91 per cent read the Journal in whole or in part. There was an equal demand for more articles written by our readers and by national figures. About 50 per cent used the book reviews in selecting such volumes and the same number used the advertising pages in purchasing drugs and supplies. Agreement with editorial opinions reached 87 per cent.

Special articles during the year dealt with the chronically ill, health in education, the medical program at Newington Hospital, operation of Public Law 725, voluntary prepaid plans in rural communities, and the Connecticut Cancer Registry. Editorials covering a wide range and up-to-date developments were emphasized in the various sections.

The subject of Prepaid Medical Care was receiving serious consideration and in May at the annual meeting of the Society there was presented the results of an outstanding comprehensive committee study of this problem. The Journal was represented on this committee by the Literary Editor. The subject of cancer was on the minds of all at this time and resulted in the first Cancer Conference for Physicians in Connecticut on March 6, 1948. In November the Journal published a Supplement containing ten articles by leaders in the field of cancer. Also in March appeared an account of the first full-scale medical practice group in Connecticut, formed in New Britain. Historical articles were becoming more frequent again after a lapse during the war. Illustrated stories featured Hartford Hospital's dedication of its new $8 million building, plans of Day-Kimball Hospital for $300,000 building fund, and the dedication of Bristol Hospital's new building. A series of Military Biographies of members of the Society was introduced in April 1948 and continued through several succeeding issues.

The Editorial Board, which had omitted formal meetings during the war, now met quarterly again. Readers were informed that the Journal was being sent to many countries overseas on an exchange basis. Extracts from all of the exchanges, both national and foreign, were compiled by Paul P. Swett. The Journal published President James R. Miller's outstanding addres on "Government and Medicine." Residency Training for General Practice appeared in September, and in the same issue postgraduate opportunities were emphasized with an announcement of the courses at Yale. An interesting first-hand account of the second annual meeting of the World Medical Association held in June appeared in the September issue. The December issue emphasized prepayment medical service with Connecticut Medical Service (CMS) outlined in detail. The Journal offered subscriptions to "Medicine of the Year," a series of articles on medical progress, as a continuing supplement to the Journal. These were later published in book form. Benjamin White of the Board contribued an article, "Screening as a Viewpoint in Medical Practice."

Bids were let out in 1948 for the Society's building. The Literary Editor was now serving on the Committee on Post-Graduate Medicine and Tumor Study. The detailed account of each meeting of the House of Delegates was not printed following the war due to lack of space, but actions taken by the Council and the House were always reported. Due to a drop in advertising, the Journal had a deficit for 1948 of $4,500 with an increase at the same time of the Society's membership to 3,000, resulting in a per capita cost to the Society of $1.50 in 1948.

The postwar years were marked by many new and interesting features. In January 1949 appeared the first article on "Natural Childbirth" by the Literary Editor, Dr. Thoms. CMS began its enrollment of physicians. Original papers by members of the Society covered such subjects as "Fluid Balance and Intravenous Therapy." Another first was a paper on the "Treatment of Tuberculosis with Streptomycin." An increasing financial crisis int he hospitals was editorialized in April 1949. Benjamin White of the Editorial Board wrote on "Lipotropin Agents and Sulfur-Containing Amino Acids." AMA began a campaign against compulsory health insurance and this was reflected in a new section in the Journal as well as editorial comments. The Physicians' Art Exhibit was illustrated in the Convention Number with copies of paintings by Harold Burr of the Editorial Board. In June 1949 Dr. Barker supplied biographies and photographs of the Connecticut members of Congress. For the first time there appeared a discussion of licensure of foreign medical graduates. Many bills on the Welfare State were introduced into Congress that year. A change in the name of the section on Campaign against Compulsory Health Insurance was made to Educational Campaign. The Editor-in-Chief contributed an article on "Child Health Service in Connecticut."

On August 25, 1949 the Society moved into the new building and in October a special issue contained several articles well illustrated, in addition to photographs of the Trustees of the Building Fund and lists of memorial gifts and of all the contributors. Harold Burr added an historical article on the Connecticut State Medical Society.

That same year the Literary Editor was invited to attend the meetings of the Council and Benjamin White was elected an alternate delegate to the AMA. The House of Delegates voted to send copies of the Journal to the secretary of each County Woman's Auxiliary. Advertising increased and so did the cost of publication to the extent that there was a deficit in 1949 of $8,000.

Again our nation was involved in war, this time in Korea beginning in June 1950. The Doctor Draft Bill, operating under the Social Security Service Act, was amended, and again physicians from Connecticut were subject to military service. The Journal suffered the loss by death of Paul P. Swett, who supplied the section on Our Exchanges. Marshall S. Pease of Ridgefield was selected to fill the vacancy. A new section, The Historian's Note-Book was added with contributions thereafter from George Blumer, Arthur S. Brackett and the Literary Editor. In this section appeared two historical papers, "The New London County Medical Association" and "Colchester's Most Distinguished Physician." A regional hospital council was proposed for Connecticut. The section on Medicine and the Veteran was dropped. Annually in the February issue appeared the Charter and By-Laws of the Society, and in the August issue, the Roster of Members. A new local advertising representative was secured, the previous one being unsatisfactory.

To the Editors and Board the outstanding event was the moving of the Journal office in August 1950 to the Society's new building in New Haven. This made necessary the securing of a new Assistant to the Editor. Mrs. Vivian C. Feriola was selected from a number of applicants and has served the publication faithfully to this date. The Journal suffered another serious loss that year when C. Charles Curlingham died suddenly while in London. He had been a staunch supporter of the Journal as well as a frequent contributor and a reviewer of many books in the field of psychiatry.

Manuscripts were submitted in increasing numbers during 1951. They covered such subjects as the new contract of CMS; early medical practice in Waterbury; the site of the Society's annual meeting; drug addiction; preventive geriatrics; civil defense; Yale rooming-in plan; increase in Cesarean section; subtotal hysterectomy, and screening in the physician's office. An account appeared of the World Medical Association meeting in New York at which the Editor-in-Chief was one of the speakers. There were many articles on health legislation and socialized medicine. The Convention Number carried an historical sketch on Stratford and another one on "Some Connecticut Medical Naturalists" by the Literary Editor. For the first time there was a discussion of premarital counseling and included was "Medical Care for the Indigent, the Aged and the Blind." Hospital construction was enjoying a boom in our State, St. Francis Hospital dedicating its new building. The Connecticut Regional Blood program was described in June, and the Matching Plan for interns was editorialized in November. Arthur Geiger resigned as News Editor from Yale Medical School in 1951.

Interest in the Korean War was increasing with the result that a new section on Military Affairs was added. "The Medical Aspects of Atomic War" had its place in the December issue. Medical Reserve Officers to the number of 250 were ordered to duty in the U.S. Army.

In the following year of 1952 the May issue was characterized by scientific papers solely on tuberculosis. In another issue appeared an article on the "Connecticut Plan for Medical Care of Veterans." An unusual feature one month was four pages of statements by the Presidential and Vice Presidential candidates and the Congressional candidates from Connecticut. During the year the subject of medical education occupied a prominent place when the AMA formed its Medical Education Foundation. Federal aid for this worthy cause was advocated. The Roster of Members now appeared as a separate Supplement to the August issue. Note was taken that the number of judgments against physicians was becoming an ever increasing problem. CMS, in a section devoted to that organization, reported an enrollment of 500,000.

Benjamin White resigned from the Board and was replaced by Clair Rankin of Hartford, who assumed responsibility for the section on Progress in Clinical Medicine. The Editor-in-Chief was again elected a delegate to the AMA, and the Literary Editor was on leave during the year because of illness. Many of the editorials now were written by the Society's Secretary, who kindly stepped in to fill the breach. For the first time the Chicago Conference of Editors and Business Managers of State Medical Journals was conducted by the State Journal Advertising Bureau instead of by the AMA and the Connecticut Journal was given the honor of arranging the program. The aims and accomplishments of these journals were editorialized for our readers. Reserve medical and dental officers were returning from the Korean War in increasing numbers and being replaced by others called up under the draft. Hospital admissions were increasing, with the length of patient stay diminishing. The Journal called attention to the "vanishing dollar" and at the same time reported a profit of $600 for the year and income from subscriptions outside the Society of $1,000.

A résumé at the beginning of each scientifc paper was added in 1953, and a new section appeared on the Clinical-Pathological Conference. The Journal reported on the new committee appointed by the AMA to evaluate the status of the internship and medical education. The question of a second medical school in Connecticut was discussed in an editorial The problem of improvement in medical care in Connecticut resulted in the appointment of a State committee to study the same. For the first time in history, in 1953, the President of the AMA addressed the Connecticut Society's House of Delegates. At the Council meeting in October the future operation of the Journal was discussed at length and a special committee selected to conduct a study. On this committee were H.M. Marvin, Chairman, C. Louis Fincke and John Gallivan.

In July 1953 the Korean War was officially terminated. A new VA Hospital was opened in West Haven. The First World Conference on Medical Education was reported from London. Reciprocity of licensure between the States was discussed and CMS decided to terminate its agency agreement with Blue Cross. The Journal published an editorial on the future of osteopathy. The State Medical Society embarked upon a program of grants, the first scholarships going to Schools of Nursing. The subject of fluoridation appeared both in a scientific article and an editorial. A full-time State Department of Mental Health was formed, and again there was discussion of the Physician-Hospital Relationship. The Literary Editor resigned from the Yale Medical School faculty as of December 31, 1953.

Following suggestions made by the ad hoc committee charged with studying the operation of the Journal, a change in the by-laws increased the number of the Editorial Board in 1954 to 15, made the Editor-in-Chief Managing Editor and made the Literary Editor Chairman of the Board. The increse in the Board was designed to represent, as widely as possible, geographical and specialty groups.

The 1954 Convention Number covered the event with illustrations, the program, and photographs of all the speakers. In addition the Hartford Hospital's 100th anniversary was featured, and for the first time there was an article on "Tobacco Inducing Cancer" with an accompanying editorial. Hospital charges were explained, prevention of malpractice suits was urged, and there appeared increasing interest in plans for retirement. Social

Security for physicians wa occupying more and more space, with discussion both pro and con. Editorials on socio-economic and public health problems incresed, and there was more interest in the health problems of the aged. Medical catastrophic insurance was now available. Scientific papers by members showed a definite increase. The attendance at the annual Clinical Congress was steadily declining, and, as a result, the Council decided to send out a questionnaire in order to determine the future of the Congress. The deficit for the Journal for 1954 was $2,800, less than one dollar per member.

Herbert Thoms resigned as Literary Editor and was succeeded by H.M. Marvin in 1955. Thomas Markie of Westport, a member of the Editorial Board, died in October of that year while in active practice. Both advertising copy and scientific papers increased and the Journal deficit was reduced to approximately 50 cents per member. The various regional news sections were combined into one, Around the State. The Board offered a prize in 1955 for the best manuscript submitted by a member of the Society. The Literary Editor was made the Society's representative on the committee to arrange the program of the AMA's Clinical Session to convene in Boston in November. A new section, Our Medical World, was authored by a member of the Society. During the year, articles were published on the practice of medicine by hospitals, professional liability insurance, with an editorial, the Society's employment program, and on addiction with an editorial. A second medical school in Connecticut was editorialized following an exhaustive report by a committee appointed by the Governor.

It had become apparent that additional space was required in the new building to house all the activities of the Society and some of its related organizations. For this reason, on recommendation of the Council, the House of Delegates voted to proceed with such in 1955. Funds for this purpose were to be obtained by voluntary contributions to the Trustees of the Building Fund.

Following the death in 1956 of Dr. Gold, former president of the Society and Chairman of both the Council and the Trustees of the Building Fund, the James Douglas Gold Number in August contained a collection of scientific articles on dermatology, his chosen specialty. The loss of this fine gentleman was felt keenly by all. Unselfish in his devotion to the interests of physicians and the practice of medicine in Connecticut, he had endeared himself to everyone with whom he came in contact. It was only fitting that, when the addition to the building was completed, one of the conference rooms should bear his name. At this time other conference rooms were named for Dr. Barker and Dr. Weld.

A new section appeared in the Journal in January 1956 called Insurance and the Physician. The section on Medicine and the War, later named Military Affairs, was discontinued. Medicare was in the planning stage with a committee appointed to set up fee schedules. There was much discussion of Social Security for physicians, opposed by the AMA. Cancer was considered in several articles and editorials. The subject of medical malpractice insurance appeared again, and there was an article on "Corporate Practice in Connecticut." The Journal had a good year, with many Board meetings well attended. The closing paragraph of the Managing Editor's report for 1957 expressed well the ideals of the editorial staff:

> Osler's aphorism is worthy of repitition. "The artistic sense of perfection in work is a much-to-be-desired quality to be cultivated. No matter how trifling the matter in hand, do it with a feeling that it demands the best that is in you, and when done look it over with a critical eye, not sparing a strict judgment of yourself.

In 1957 there were murmurings from the Society members which reached the ears of the editors. At first the criticisms seemd based on the cost of the Journal. Some wanted a more modest publication, others, only a house organ. Some wanted this section omitted, and some, that section. The Manging Editor gave his reasons for the size of the Journal as follows: its purpose was (1) to keep its readers informed of the latest developments in medicine in Connecticut and the U.S.; (2) to keep its readers informed of all the activities of the State Society and the County Associations; (3) to afford members an opportunity to develop scientific interest and literary talent; and (4) to maintain the proper proportion between printed matter and advertisements. It was explained that 10 years ago no color advertisements and no inserts were used. Now there was much of both. The cost of labor in the production of the Journal had increased considerably, in part due to these new processes. This is reflected in the deficit of $4,400 for 1957.

In July of that year a special Thomas P. Murdock Number appeared containing 13 papers by him alone and three as co-author. These were preceded by many resolutions and tributes to him. Dr. Murdock's untimely death in the prime of life earlier that year was a great blow both to the Society and to the Journal which he had ardently supported. Thom Murdock was a hard worker devoted to his profession and to his fellow physicians. His ability was recognized nationally and his services at home were rewarded by many positions of responsibility.

This year, 1957, the journal carried in one issue, as directed by the Council, two papers on Social Security for physicians, one for, the other against. The AMA House of Delegates continued to oppose this plan. The following month there was surprise when the results of a questionnaire on this problem resulted in 73 per cent of those replying in favor and 26 per cent opposed. Several articles on Medicare were published by the Secretary of the Society during the year. This was the 10th year of the report from the Connecticut Cancer Conference. There was discussion of cooperation by the Society with the State Bar Association. The section on Public Relations was now being provided by a committee following the resignation of its director. There were two articles on the hospital practice of medicine, and reports continued to appear from the Committee to study Maternal Mortality and Morbidity. The World Medical Association sessions were being reported each year and travel articles by different members appeared at frequent intervals.

The new Connecticut Blood Program was outlined in one of the 1957 issues. G.B. began a series of editorials on Smoking and Health and for the first time automobile safety belts were mentioned. A new section was allotted to the Committee on Medical Care of Veterans. Notice was taken of the organization of general practitioners in our State, and the many problems of retirement were discussed in an editorial. Marshall Pease of the Editorial Board was honored by an award from the American Academy of Pediatrics. The issue of December 1957 was the last issue to be printed by Whaples-Bullis Company.

The year 1958 was a memorable one for the Journal. In January appeared the first issue by a new printer in New Haven. H.M. Marvin resigned as Literary Editor and was succeeded by Allan J. Ryan of Meriden. Marshall Pease also resigned in January, moving to California because of his wife's health, and Dr. Marvin replaced him as editor of the section Our Exchanges. That same month Donald P. Bullis died of multiple myeloma. An interesting article appeared on "When To Use and Not To Use Antibiotics." Three new sections were formed, Connecticut Medical Service, Committee on Accident Prevention, and Committee on Perinatal Mortality. The June issue featured St. Raphael Hospital's Golden Jubilee.

When the Conventional Number appeared in April 1958 the Managing Editor had little idea of what lay ahead. Discussion between CMS and the Society had reached the point where there were all kinds of arguments, primarily among the physicians themselves over fees for various medical servies and procedures which prevented any reasonable progress with CMS and which were the source of far-reaching antagonism. A feeling of resentment against all officers of the Society took hold with the result that there arose a group who felt the best solution was to clean the entire slate and replace it with new faces, preferably among the younger members of the Society. This was done at the meeting of the House of Delegates in Stratford on April 29, 1958, where, among others, the Secretary of the Society and both Editors of the Journal were not re-elected. The following July the name of the Journal was changed to *Connecticut Medicine.*

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Pancreatic Transplant Following Total Pancreatectomy for Chronic Pancreatitis:

Report of a Case and Literature Review

DAVID S. SEAMAN, M.D. AND KENNETH A. CIARDIELLO, M.D.

ABSTRACT – Three hundred fifty pancreatic transplants have been performed since 1965 with less than 4% done for relief of diabetes secondary to pancreatic resection for chronic pancreatitis. In the present study, a 43 year old female with proximal pancreatic duct stenosis underwent total pancreatectomy followed by transplantation of 60% of the gland to the left groin. Anastomosis of the splenic vessels to the femoral vessels completed the procedure.

The patient was studied for bilateral femoral vein insulin levels which revealed a left-sided value of 23uU/m1 versus 12uU/m1 on the right side. A 24 hour urine C peptide assay resulted in 14.3 nmol with normal nondiabetic subjects displaying 11.6± 3.5nmol. A selenium 75 scan showed accumulation of isotope in the left groin, indicating active perfusion of the graft.

These results indicate that this procedure may be useful in maintaining endogenous insulin levels which may help alleviate the secondary effects and hyperglycemia of diabetes mellitus following total pancreatectomy.

Introduction

The first attempt at pancreatic transplant was done in 1966 for relief of uncontrollable diabetes in a 28 year old female.[1] Since that time, approximately 350 transplants have been performed in several institutions worldwide.[2] Only eleven to date have been done following near total and one following total pancreatectomy for chronic pancreatitis. The purpose of this communication is to present an additional case of transplant following total pancreatectomy for pancreatitis and to discuss the implications.

Patient Profile

The patient is a 43 year old white female with a 10-year history of alcohol abuse and a 40 lb. weight loss over the past year, who presented with acute pancreatitis. Workup revealed this to be secondary to chronic relapsing calcific pancreatitis. Ultrasound and upper GI series delineated a pseudocyst in the head of the pancreas. Endoscopic retrograde cholangiopancreatogram revealed a narrowed common bile duct and stenosed, irregular pancreatic duct. Both the distal common bile duct and pancreatic duct were severely diseased in the ampullary region. An attempt at conservative treatment failed and she underwent a cystduodenostomy for internal drainage of the pseudocyst. During the procedure, a cystogram showed the distal duct in communication with the pseudocyst. She did well postoperatively but returned six weeks later with continued, intractable abdominal pain. Due to severe uncontrollable pain partially relieved by narcotic only, the results of the previous roentgengrams, unsuccessful internal drainage and the need for constant hospitalization and hyperalimentation, the patient underwent total pancreaticoduodenectomy, splenectomy, primary end-to-side duodenojejunostomy and choledochojejunostomy. The distal 60% of the pancreas was transplanted to the left groin.

During the dissection, the distal branches of the splenic vessels feeding the body and tail of the pancreas were carefully preserved. Anastomosis of the distal splenic artery to the superficial femoral artery and splenic vein to femoral vein completed the procedure. The pancreatic duct was suture ligated subsequent to infusion with 2cc of a synthetic polymer (Neoprene). Histologic examination of the pancreas revealed both chronic and acute pancreatitis with extensive fibrosis replacing most of the normal parenchyma. In addition, there was marked atrophy of acini and islet of Langerhan complexes.

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This paper was presented at the December 3, 1985 meeting of the Connecticut Society of American Board Surgeons.

Postoperatively, the patient developed an intra-abdominal abscess requiring drainage on postop day #22. In addition, a pancreatic fistula developed in the left groin. This required local drainage but eventually closed. The patient developed glucose intolerance approximately one week postoperatively requiring exogenous insulin. Stabilization of insulin requirements at 22u NPH and 6U regular every morning has since occurred. Insulin levels taken at the iliac veins bilaterally revealed values of 23uU/cc on the left (grafted) and 12uU/cc on the right (nongrafted). Four years post-operation, the levels are 16uU/cc on the left and 6uU/cc on the right. A 24 hr. urine C-peptide assay resulted in a value of 14.3 nmole (normal 11.6± 3.5 mole). Finally, a selenium 75 scan revealed increased uptake of isotope in the region of the graft.

The patient is currently stable on 22u NPH and 6U regular insulin every morning. She has completely reformed from her alcoholism and has returned to a state of well being.

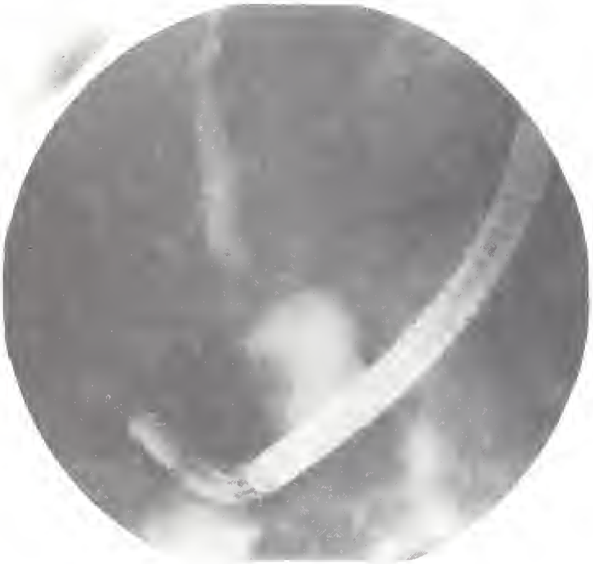

Figure 1
Endoscopic retrograde cholangiopancreatogram illustrating extensive periampullary disease and a stenosed distal common bile duct with proximal dilation. Note the pseudocyst in communication with the ductal system. Accessory pancreatic ducts, consistent with main pancreatic duct occlusion, are also seen.

Discussion

Since 1966, pancreatic transplantation has been performed for relief of diabetes mellitus. Only 11 or roughly 3% of these have been done following total or near total pancreatectomy for chronic pancreatitis refractory to all medical treatment. This radical procedure is fraught with major postoperative problems, the most important of which is diabetes and glucose intolerance, with its attendant 25-40% major morbidity or mortality.[3,4]

Pancreatic transplants may be separated into two main categories. The first involves injection of isolated and purified pancreatic islet cells into the portal vein. The objective is to allow the islet cells to be entrapped and grow at selective sites in the liver, setting up an endogenous supply of insulin. This technique has been universally unsuccessful, with complications including portal hypertension, DIC, systemic hypertension and rejection.[5,6] Rarely, acute portal vein thrombosis occurs with subsequent death.

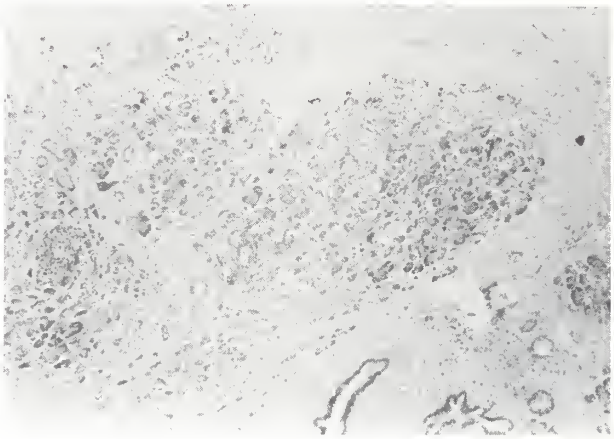

Figure 2
Histological section of the resected portion of pancreatic head displaying severe fibrosis and loss of regular gland architecture. The exogenous insulin requirements are likely due to the severity of disease as depicted here.

The second technique utilizes a pancreatic autograft or allograft of the body and tail of the gland. The splenic vessels are dissected with the gland, taking care to preserve the small perforating vessels feeding the distal 60% of the pancreas. In a postmortem study, it was found that most glands are adequately perfused by these perforators.[7] The gland is then transplanted either intraperitoneally or extraperitoneally. If the latter location is chosen, the implant may be either in the abdominal wall or groin. Anastomosis of the splenic vessels to the iliacs or the femoral vessels complete the procedure. It is important that these grafts be sewn without twists in the anastomosis, as these often lead to immediate venous thrombosis.[8] Practically, the most difficult aspect of the technique involves the pancreatic duct and the exocrine secretions.[9] To date, several different procedures have been described including duct ligation, open drainage of the duct into the peritoneum,[10] ductoenterostomy,[11,12] ductoureterostomy,[13] and ablation of the duct with a synthetic polymer (Neoprene).[7] The latter technique has become the most popular with 2-8cc of material injected just prior to transplant. A further objective of injection is to initiate a fibrosis of the acinar tissue while leaving the islet cells unaffected. Complications of Neoprene injection include pancreatitis, fistula formation, and gland necrosis.[7]

In the previous 11 patients reported, all of the transplants were autografts and were implanted in the groin.[9,14,15,16] Most of these patients had a history of alcohol abuse. The majority had undergone complete biliary workup including CT scans and pancreatography prior to surgery. Only two reported cases have been done with total pancreatectomy (including the present case), with the remaining cases being 85-95% pancreatectomies. This fact bears some importance as to confirmation of the insulin producing capability of the remaining tissue for in near total pancreatectomy patients, the 5-15% remaining pancreas may be responsible for the circulating active insulin.

Implant viability was assessed by several means. These include angiography, isotope scans, glucose tolerance testing, simultaneous bilateral serum insulin assay and C-peptide assays. Most groups have reported a 2-30 fold difference in insulin levels between the grafted and nongrafted sides.

In the present study, a selenium 75 scan was performed three months posttransplant which revealed a slight increase in uptake over the graft. It is important to note that this scan relies on viable exocrine tissue for positivity. Neoprene injection into the pancreatic duct network results in fibrosis and ultimate death of a good portion of the exocrine tissue. Therefore, the selenium scan should show progressive decrease in uptake consistent with smaller numbers of functioning acini. The bilateral insulin levels two months postoperatively were 23uU/cc vs 12uU/cc or approximately 2:1 indicating production of hormone from the graft. Four years postoperatively, the values are 16uU/cc on the left and 6uU/cc on the right. The C-peptide 24 hr. assay was normal. This latter result is the most positive evidence for hormone production.

Despite the good results, the patient still requires exogenous hormone. This is likely due to the severity of pancreatic disease with marked fibrosis and decreased number of islet cells in the implanted pancreas. The fact that the patient does not display the brittle diabetes so characteristic of total pancreatectomy is suggestive of the presence of some endogenous hormone production.

The main objective of pancreatic transplant is to reverse the diabetic effects of total pancreatic resection.[5,10] Furthermore, the hyperglycemia is not as important as the secondary effects including peripheral vascular disease, retinopathy, neuropathy, and small vessel disease.[14] If these severe secondary effects are eliminated or at least postponed by the graft endogenous hormone, the procedure has been successful in meeting its objective with acceptable additional morbidity to the patient.

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The Value of Cryo-Preservation of Parathyroid Tissue

MICHAEL M. FUENFER, M.D., LUDWIG J. PYRTEK, M.D., LAINE KRISIUNAS, M.T.
AND ROBERT T. SCHWEIZER, M.D.

ABSTRACT – Treatment of parathyroid hyperplasia requires extensive resection of parathyroid glands. The function of remaining tissue may be inadequate, necessitating life-long calcium and vitamin D supplementation. Excised glandular tissue may also be autotransplanted into the patient's forearm at the time of the original operation, or this procedure may be delayed until post-operative endocrine function can be ascertained. In either instance, a portion of the resected specimens should be cryopreserved for later use in the event of hypoparathyroidism.

Since 1979, the service of cryopreservation has been provided by our laboratory for 49 patients from several New England hospitals. Three of these patients subsequently underwent autotransplantation with good results. We present the case of a patient with primary hyperparathyroidism who became hypoparathyroid following ablative surgery. She returned to a euparathyroid state after forearm autotransplantation of cryopreserved tissue.

Case Report

G.R. (HH #2390487) was a 21-year-old female when she presented to a Houston, TX clinic in 1978 complaining of right flank pain radiating into the right groin. Urine analysis demonstrated microscopic hematuria, a radiograph of her lower abdomen showed the presence of 15 stones at the ureteropelvic junction and three stones in the right ureter. Serum calcium was 11.6 mmol/L (normal=8.8 - 10.4) and serum phosphorus was 2.9 mmol/L (normal=0.8 - 1.5). A diagnosis of primary hyperparathyroidism was made and a hyperplastic right superior parathyroid gland was removed. She remained hyperparathyroid when seen in Hartford in 1982. Serum calcium was 10.9 mmol/L and urine calcium was 315 mmol/L (normal=100 - 250), parathyroid hormone (PTH) level was 85 ng/L (normal=40 - 100).

The left superior, left inferior, and 75% of the right inferior parathyroid glands were removed at surgery in 1982. The pathologic diagnosis was chief cell hyperplasia. All surgical specimens were cryopreserved. Postoperatively, she developed symptomatic hypocalcemia requiring calcium and vitamin D supplements. In 1984, 20 separate pieces of cryopreserved parathyroid tissue were implanted into five forearm muscle pockets. Medications were discontinued postoperatively, and one month later serum calcium was 9.4 mg/dl, phosphorus was 2.8 mg/dl and PTH was 312 ng/L, (normal=61 - 316). Two years later she remains asymptomatic with normal calcium homeostasis.

Discussion

William Halsted performed the first successful autograft of canine parathyroid tissue in 1908.[1] However, it was not until 1977 that Samuel Wells demonstrated functional viability of human parathyroid tissue which had been cryopreserved for six weeks.[2,3] Glandular function was documented by a return of previously low serum calcium levels to normal, differential elevation of venous blood samples for PTH in the grafted versus non-grafted forearm, and normal histology of glandular tissue by light and electron microscopy.

The principle indications for cryopreservation are initial parathyroidectomy for multiple gland disease (primary or secondary) and re-operation on patients with single gland disease.[4] Controversy exists regarding simultaneous versus deferred autotransplantation. However, even if the removed glands are immediately implanted into the forearm at the time of the original operation, some tissue should be retained for cryopreservation. Although the success of fresh grafts is usually reliable in experienced hands, preservation may prevent a permanent hypoparathyroid condition postoperatively by providing viable parathyroid tissue for autotransplantation. Initial operations for single gland disease and unintentional devascularization do not normally require tissue cryopreservation. The incidence of hypocalcemia following removal of a single gland is very low, and inadvertantly devascularized parathyroid tissue should be grafted immediately.

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Presented at the Annual Meeting of the Connecticut Chapter of the American College of Surgeons, Cromwell, CT, December 4, 1985.

Without cryopreservation of excised parathyroid glands, patients may be in jeopardy for permanent hypoparathyroid function. We have recently encountered several patients rendered permanently hypoparathyroid following ablative surgery for parathyroid gland hyperplasia and unsuccessful immediate autotransplantation. Cryopreservation had not been performed in any of those patients.

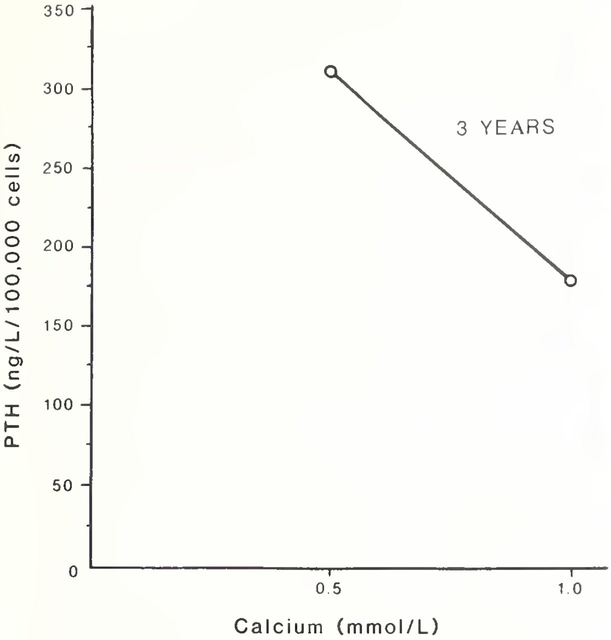

Figure I
In vitro calcium-induced suppression of PTH from parathyroid tissue cryopreserved for three years. Less PTH was produced from the cultured tissue in the media with a higher concentration of calcium, indicating a normal homeostatic response.

The technique of cryopreservation is uncomplicated, inexpensive, and the retention of functional tissue viability of cryopreserved parathyroid tissue has been documented clinically and histologically both in our laboratory and by others.[5,6] We have demonstrated good functional viability of parathyroid tissue cryopreserved for three years by an in vitro assay of PTH suppressibility in response to ambient calcium concentration. (Figure 1) Light and electron microscopy of these glands also showed excellent preservation of cell ultrastructure. (Figure 2) Patients undergoing certain types of parathyroid reduction surgery in which preservation of normal calcium hemeostasis may be jeopardized should have cryopreservation of the excised tissue until maintenance of normal endocrine function has been established post-operatively.

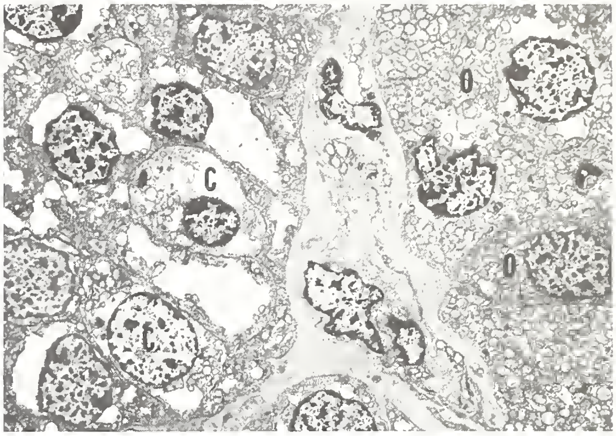

Figure 2
Transmission electron micrography of parathyroid tissue cryopreserved for three years (x 4800 magnification). Normal cell ultrastructures of chief (left) and oxyphil (right) cells are demonstrated.

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Verapamil Responsive Ventricular Tachycardia

RONALD PARISER, M.D. AND JEFFREY KLUGER, M.D.

ABSTRACT — A young patient with an unusual form of ventricular tachycardia (VT) is described. The patient's clinical stability and verapamil's efficacy in management led to the initial clinical impression of a supraventricular tachycardia. Electrophysiologic evaluation revealed a verapamil responsive VT with a right bundle branch block and left axis deviation QRS morphology. Non-invasive and biopsy studies support the absence of apparent organic heart disease. The VT in this patient may represent a unique clinical entity with specific electrocardiographic and electrophysiologic properties.

Verapamil's inhibition of slow channel mediated conduction in the atrioventricular (AV) node has resulted in considerable efficacy in the management of supraventricular tachycardia.[1] Verapamil is generally not effective in the management of recurrent ventricular tachycardia (VT) related to healed myocardial infarction.[2,3] Idiopathic recurrent sustained VT with a QRS pattern of right bundle branch block (RBBB) and left axis deviation (LAD) in young adults with no obvious heart disease has recently been reviewed.[4] Prevention or termination of this VT with verapamil has been noted by several authors.[4-8] We describe a patient with recurrent sustained VT of a RBBB and LAD QRS morphology responsive to verapamil and briefly discuss this unusual form of VT.

A 36 year-old normotensive man was evaluated because of a recurrent symptomatic sustained tachycardia. The patient was well until 8 months prior to admission when while resting after bowling he developed pounding in his chest and lightheadedness persisting overnight. An electrocardiogram (Figure 1) during the tachycardia demonstrated a RBBB and LAD QRS configuration at 210 beats/minute. Verapamil slowed and then converted the tachycardia to normal sinus rhythm over several hours. A new RBBB and inferolateral T wave changes were noted after conversion, but a follow-up electrocardiogram one month later was normal. One month later a repeat episode of palpitations occurred while driving which converted after two doses of 80 mg of verapamil by mouth. One month later the patient was electively admitted for the surgical

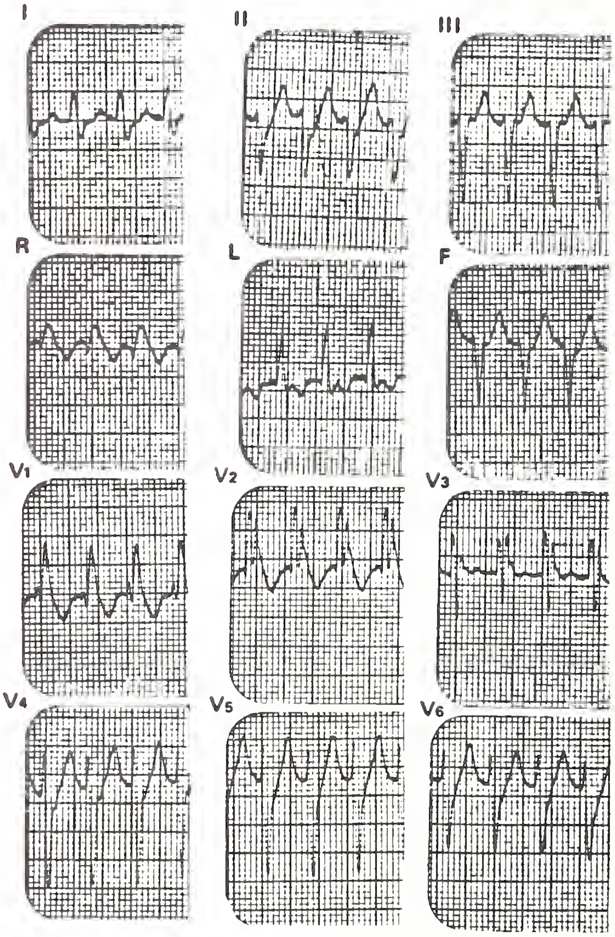

Figure 1
Twelve lead electrocardiogram during ventricular tachycardia showing a QRS pattern of right bundle branch block and left axis deviation during a spontaneous episode at 210 beats/min.

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correction of a left inguinal hernia. Preoperatively while reading a book, the patient's tachycardia recurred, the blood pressure was 140/110, and the tachycardia was unresponsive to lidocaine. Propranolol and procainamide decreased the rate to 120 beats/minute revealing AV dissociation. Verapamil converted the tachycardia to normal sinus rhythm with a RBBB, and the patient was transferred for evaluation.

Physical examination on no medication revealed a blood pressure of 120/70, pulse of 80, and a reducible inguinal hernia. Routine laboratory evaluation was normal including thyroid function, potassium, calcium, and magnesium. Non-invasive cardiac evaluation included a normal treadmill test (stage 5 of the Bruce protocol), a normal M-mode and 2D echocardiogram, and a normal gated radionuclide angiogram of the left (ejection fraction 74%) and right ventricle. The echocardiogram did not reveal mitral valve prolapse, and neither the echocardiogram nor the gated study revealed wall motion abnormalities. A 24 hour Holter monitor revealed 5 supraventricular premature beats. Electrophysiologic assessment was performed using standard techniques[9] in the nonsedated state 48 hours after discontinuing verapamil which had been given for the recent episode of tachycardia. The baseline electrocardiogram revealed a typical RBBB with an inferior axis and T wave inversions in V1-3. Sustained VT at 200 beats/minute of a RBBB and LAD pattern was induced with rapid atrial pacing and double premature ventricular stimuli during sinus rhythm (Figure 2). This VT was similar in rate and configuration to the patient's clinical tachycardia. Lidocaine, procainamide, and propranolol slowed but did not prevent the induction of sustained VT. After administration of verapamil (480 mg/day) for 96 hours only nonsustained VT (maximum 5-12 beats) at 115 beats/minute was inducible from 2 right ventricular sites using 3 ventricular stimuli and rapid ventricular pacing. A right ventricular endomyocardial biopsy was normal by light microscopy.

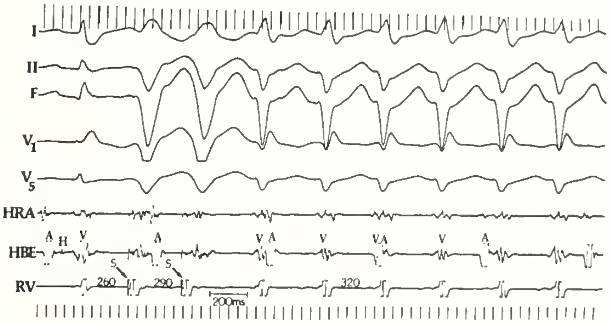

Figure 2

Recording showing the induction of ventricular tachycardia (VT) with 2 premature ventricular stimuli during sinus rhythm. Note the right bundle branch block and left axis deviation QRS morphology of the VT. AV dissociation is present during the VT. The VT cycle length was 320 mg and the coupling intervals of the premature ventricular stimuli were 260 and 290 mg. A = atrial electrogram; H = His bundle recorded during sinus rhythm; HBE = His bundle electrogram; HRA = high right atrial electrogram; S = premature ventricular stimulus; RV = right ventricular electrogram; V = ventricular electrogram.

On oral verapamil (480 mg/day) for 12 months, the patient has done well.

This patient's wide QRS (.12 MSEC) tachycardia was initially diagnosed as supraventricular because of verapamil's ability to convert the tachycardia to normal sinus rhythm. Findings suggesting a ventricular origin of the tachycardia include left axis deviation, AV dissociation, and an R:S ratio of less than 1 in lead V6 in the presence of a RBBB.[10] The VT described in this patient shares the following features noted by others:[4-8] 1) occurrence in young patients without apparent organic heart disease, 2) a RBBB and LAD QRS pattern of the VT, 3) inducibility with ventricular and occasionally atrial stimulation, 4) response to verapamil, 5) unexplained repolarization abnormalities inferolaterally, and 6) nonresponsive to lidocaine and propranolol. The ability of programmed stimulation to initiate and terminate these VT's combined with verapamil's efficacy suggests reentry involving slow channel dependent tissue[5,6,11] or triggered automaticity.[11-12] Endocardial mapping suggests the site of origin of the VT in the inferoapical or posteroseptal left ventricle.[4-6] Previous descriptions of these patients have not included biopsy results.[4-8] Biopsies have been abnormal in a high percentage (90%) of patients with life-threatening ventricular arrhythmias without apparent structural heart disease, but have not described comparable patients. Abnormalities noted included nonspecific cardiomyopathy, fibrosis, right ventricular dysplasia, myocarditis, and vascular abnormalities.[13,14] This patient may have a unique form of VT in the absence of apparent organic heart disease which is supported by the normal non-invasive and biopsy studies.

Although verapamil was previously considered exclusively a drug of choice for supraventricular arrhythmias, evidence for considerable efficacy exists in young patients with sustained VT of a RBBB and LAD QRS pattern in the absence of apparent organic heart disease.[4-8] Verapamil has also been successful in preliminary studies involving VT during the early phases of myocardial infarction,[8] on exercise-triggered VT,[8,15] and in a group of patients with no demonstrable heart disease and polymorphic VT with a normal QT interval.[8] In contrast, verapamil for VT associated with recent or late myocardial infarction has generally not been effective and can be deleterious. Sung administered verapamil to 8 such patients and noted verapamil induced hypotension requiring cardioversion in 3.[16] Buxton noted that in 11 patients with nonsustained VT, verapamil accelerated and prolonged the duration of the VT requiring cardioversion in 2 patients due to ventricular fibrillation.[17] For most patients with recurrent sustained VT, verapamil is not effective and can be deleterious.

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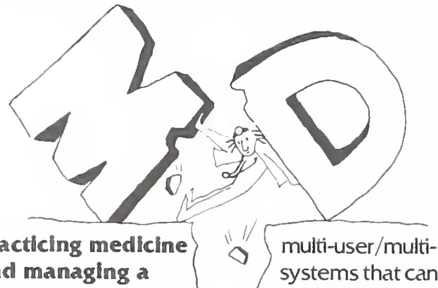

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A Comparative Study of Transparent Versus Dry Sterile Dressings for Central Venous Catheters

RON GUGLIOTTI, M.S.P.H., ABDELAZIZ RICHI, M.D., INGRID BUSWELL, R.N.
AND LINDA BURKUS, R.N.

ABSTRACT – A prospective randomized study was conducted in a 14 bed medical/surgical Intensive Care Unit to assess colonization rates of transparent polyurethane dressings compared to dry gauze dressings placed over central venous catheter insertion sites. Cultures were taken of CVP line and the insertion site. A total of 32 catheters in 30 patients, representing 56 paired cultures, were studied. Two patients were entered twice. Seven of 56 paired cultures were positive for bacterial colonization (12.50%). Five cultures grew S. epidermidis and 2 grew Pseudomonas aeruginosa. One catheter colonized with Pseudomonas aeruginosa became infected during the study for an infection rate of (3.13%). Twenty-seven of 32 catheters (84.38%) were in for less than 96 hours, average 3.10 days. No catheter was in place longer than 120 hours. There was no statistical difference in the colonization rates for all dressings studied. For CVP catheters a dry sterile dressing, changed every 72 hours or a transparent polyurethane dressing changed every 7 days are the most cost effective methods for dressing central venous catheter insertion sites.

Introduction

Wilson[1] popularized the use of subclavian catheters as a method for monitoring central venous pressure in 1962.[1] In addition to pressure monitoring, central venous catheters have been used to deliver total parenteral nutrition and a variety of fluids and blood products.

Complication rates associated with the use of central venous catheters have been reported to be as low as 0%[1] and as high as 21%.[2] Most reports of complication rates range from 1 to 7%. Complications associated with central venous catheters may be divided into mechanical or infectious problems. In a study by Eisenhaur[3] the over all complication rate was 13.7%. In the same study Eisenhaur observed an infection rate of 5.2%.

Collins[4] et al. studied 213 intravenous catheters in place for an average of 2.6 days and found the incidence of positive catheter cultures to be 17.4%. There was a positive correlation between the risk of infection and the duration of catheterization. As is true with other types of catheterization (Foley catheters) the longer the catheter is in place the greater the risk of infection.

The present study was designed to assess the colonization rate of central venous catheter insertion sites utilizing a variety of dressings. The newer vinyl transparent dressings were compared to dry sterile gauze dressings in order to determine if a difference in colonization and infection rates existed.

Materials and Methods

This study was performed over a four month period in a 14 bed medical/surgical Intensive Care Unit at a 347 bed acute care teaching hospital.

Patient Population

Thirty patients were entered into the present study. Seventeen patients were medical patients and thirteen were surgical patients. There were twenty male and ten female patients. The average age of the patients studied was 67 years old. There was no significant difference in the length of catheterization in surgical versus medical patients $(P > .05)$.

Surgical Procedure

The patient was placed in the Trendelenberg position. The area around the insertion site was swabbed with copious amounts of iodine. Two percent Lidocaine was injected into the medial and lateral areas of the clavicle. A Cook needle is then introduced through the skin. A CVP guidewire is then introduced through the Cook needle. The catheter is then introduced over the guidewire. The

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guidewire is withdrawn and a catheter holder was applied and sutured with 2-0 silk. The entry site was covered with iodine ointment and a sterile dressing was applied according to random protocol. Catheters were inserted by the Surgical Resident on call at the time.

Dressing Change Procedure

Dressings were changed by the same person during the study period. Hands were washed with antiseptic and then gloved. The old dressing was removed and the insertion site was then observed for any redness, swelling, or purulent discharge. The area around the insertion site was cleansed with 70% isopropyl alcohol and then with provodone iodine swab in a circular fashion. A small amount of povidone ointment was placed on the insertion site and a new 4 x 4 dressing was applied according to the random protocol. Aseptic technique was adhered to throughout the dressing change procedure.

Cultures

Cultures were taken utilizing two sterile cotton swabs premoistened with sterile saline. All cultures were taken before the insertion site was cleansed with isopropyl alcohol and provodone iodine. The skin around the insertion site was then swabbed in a circular direction and then placed in transport media for delivery to the microbiology laboratory. The second swab was used to swab 5 cms. of CVP line from the insertion site backward. The swab was placed in transport media and transported to the microbiology laboratory for culture.

Cultures were plated on sheep's blood agar and EMB. Aerobic cultures were incubated for 48 hours in 5 to 10% CO2 at 37 degrees C. No anaerobic cultures were done. Positive cultures were reported out using a standard 1+, 2+, 3+, 4+ reporting system.

Table 1

Seven Cultures were Positive for Bacterial Growth

	DSD	*TEGADERM(R)*[1]	*OP-SITE(R)*[2]	*BIO-OCCLUSIVE(R)*[3]
# Patients	10	6	9	7
# Cultures (Paired)	16	10	16	14
Time:				
24	7 (+)[4]	5	7 (+)	6 (+)
48	3	3	6 (+)	5 (+)
72	4	1	2	2
96	1 (+)	1	1	1
120	1 (+)			

1 - 3M Company
2 - Smith-Nephew
3 - Johnson & Johnson
4 - (+) indicates positive culture

Statistical Methods

Nonparametric statistics using analysis of variance, was used to determine if a significant difference existed between the type of dressing used and colonization and infection rates. A difference of proportions test was used to determine if all dressings were utilized equally.

Results

A total of 56 paired cultures were obtained from 30 patients. Two patients were entered twice. Seven of the 56 paired cultures were positive for aerobic bacteria (12.50%). Organisms were isolated from both the CVP line and the insertion sites in all seven cases. Five patients were colonized with S. epidermidis. One patient was colonized with Pseudomonas aeruginosa. One patient was both colonized and infected with Pseudomonas aeruginosa. The infection rate was 3.13%. Twenty-seven of 32 patients had their CVP catheters inserted for less than 96 hours (84.38%) for an average of 3.1 days. No catheter studied was in place longer than 120 hours.

Utilizing nonparametric statistics analysis was made between the four dressings used and the colonization rates using an Fcr (4.76). There were no statistical differences between the colonization rates of the four dressings studied (F=3.88). (See Table 1) Again using nonparametric statistics an analysis was made between the infection rates of the four dressings studied. No statistical difference in infection rates among the four dressings studied ($P > .05$) was realized. A difference of proportions test was used to determine if a proportionally equal number of cultures were taken with each dressing studied. No statistical difference in the proportions of cultures taken among the different dressings ($P > .05$) could be found.

Other Observations

In the present study the use of dry gauze or transparent dressings provided adequate covering for CVP catheter insertion sites. In several diaphoretic patients on whom transparent dressings were used, the dressing failed to adhere and was observed to collect significant amounts of moisture. The diaphroetic patients with dry gauze dressing did not experience this problem. The major drawback of using dry gauze was the inability to inspect the insertion site.

Discussion

The use of transparent dressings for the purpose of covering CVP catheter insertion sites has not been clearly studied. The present study attempted to evaluate the efficacy of several coverings and to assess whether one particular dressing proved superior in terms of colonization and infection rates.

The major conclusion to be drawn is that all dressings studied performed satisfactorily. In a study on the colonization and infection rates associated with transparent dressings by Maki[5] (unpublished data), he found that transparent dressings could remain on for at least seven days without increasing infection rates. In patients in whom it is known that CVP catheters would be in place for extended periods of time a transparent dressing may be the dressing of choice.

The two major pathogens isolated in the present study were S. epidermidis and Pseudomonas aeruginosa. Duskin and Siegal[6] found S. aureus, Proteus sp., Pseudomonas aeruginosa, Bacillus subtilis, Strep. viridens, E. coli, and

K. pneumoniae to be the most common pathogens isolated. Collins[4] found that S. aureus, Klebsiella-Enterobacter sp. and Proteus sp. were the most prevalent pathogens isolated.

The organisms isolated in each study most likely reflect organisms inhabiting the environments of different institutions or infection at distant sites that are responsible for colonizing the CVP catheter.

With the advent of the DRG reimbursement system about to be expanded beyond Medicare patients, hospitals will be pressed to reevaluate all existing policies and procedures for cost effectiveness. The use of transparent dressing for purposes other than skin care must be evaluated in terms of the cost benefit. The present study revealed no apparent clinical or cost advantage using transparent dressings in patients with short term catheterization. Further studies involving a large numer of patients are needed to provide a clearer understanding of the role that dressings play in the prevention of central line infections.

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SPECIAL NOTICES

SECOND ANNUAL WILLIAM M. LESSER, PH.D. MEMORIAL LECTURE

October 17, 1986

Joan Borysenko, Ph.D. is the speaker for the Second William M. Lesser, Ph.D. Memorial Lecture to be held on October 17, 1986 at Waterbury Hospital Health Center. Dr. Borysenko is the Director of the Mind/Body Group at The Beth Israel Hospital in Boston, Massachusetts and is an Instructor in Medicine at Harvard. The title of her presentation is, "Research and Practice in Behavioral Medicine: Exploring the Patient's Role in the Healing Process." She will discuss current research and practice in behavorial medicine and health psychology, including the broad spectrum of stress-related disorders treated in the Mind/Body groups which she directs at The Beth Israel Hospital.

The Annual William M. Lesser, Ph.D., Memorial Lecture is given in memory of Dr. Lesser who was the Director of Psychological Training in the Division of Psychiatry at Waterbury Hospital Health Center until his untimely death in June, 1985. The Division of Psychiatry hosts this annual event by inviting distinguished psychologists as speakers. The First Annual Memorial Lecture was given in October, 1985 by Sidney J. Blatt, Ph.D., Chief of the Psychology Section of the Yale University School of Medicine. The year's presentation by Dr. Borysenko is held as a joint Division of Psychiatry and Division of Medicine Grand Rounds at Waterbury Hospital and is the first in a series of meetings devoted to behavioral medicine and health psychology. The lecture will take place on October 17, 1986 from 10:00-11:00 a.m. in the Bizzozero Conference Room at Waterbury Hospital Health Center. For more information please contact K. David Schultz, Ph.D., Director of Psychological Training, Division of Psychiatry, Waterbury Hospital Health Center, Waterbury, Connecticut 06721 or call (203) 573-6201.

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Non-Invasive Diagnosis of Deep Venous Occlusive Disease

MAGRUDER C. DONALDSON, M.D., GALE R. RAMSBY, M.D.,
WILLIAM J. DAVIS, R.R.T., GAIL K. GIBSON, B.S. AND ANN M. HETZEL, C.M.A.

ABSTRACT— A prospective study evaluated the accuracy of Doppler, impedance plethysmography (IPG) and volume plethysmography (VPG) compared to venography in detection of deep venous occlusive disease (DVT). 16 (41%) of 39 legs in 23 patients had DVT by venogram. Test accuracy for veins at or above the knee was 95% for Doppler, 92% for IPG and 87% for VPG. Accuracy for veins below the knee was significantly less for all tests. Doppler and IPG used together yielded no false negative exams for above knee disease, and sensitivity was 85% for legs and 100% for patients with clot in any vein. Complementary use of Doppler and IPG is sufficiently accurate to replace venography in diagnosing DVT under most circumstances.

Deep venous occlusion (DVT) involving the lower extremities is notoriously difficult to confirm using the history and physical examination alone. Venography was normal in 45% of patients hospitalized for DVT in one study,[1] and another[2] showed no difference in the frequency of muscle pain, tenderness, swelling and Homans' sign among groups of patients with and without proven DVT. Even in the presence of a classic clinical picture with pain, swelling and tenderness, objective testing must be relied upon to establish the diagnosis.

Venography is the oldest and most accurate test for DVT in most institutions. Less cumbersome, uncomfortable and costly alternatives to venography have also been widely applied,[3-6] answering in part the need for a rapid, simple and inexpensive screening technique for the large numbers of patients suspected of harboring DVT in most hospital and ambulatory practices. Plethysmography and Doppler ultrasound are among the most popular of these methods. Since the accuracy of these tests is somewhat dependent on subjective interpretation and operator skill, particularly in the case of Doppler ultrasound, it is important for each non-invasive vascular laboratory to establish and monitor its own performance statistics.

Table 1
OVERALL ACCURACY OF NONINVASIVE LABORATORY TESTS FOR DEEP VEIN OCCLUSION

	Limb (%)	*Patient (%)*
Doppler		
AK	37/39 (95)	22/23 (96)
BK	24/39 (62)*	
All	30/39 (77)	20/23 (87)
IPG		
AK	24/26 (92)	14/16 (88)
All	22/26 (85)	15/16 (94)
VPG		
AK	27/31 (87)	12/17 (71)*
All	22/31 (71)*	9/17 (53)*

P <0.001 in all instances except at asterisk

Materials and Methods

A prospective protocol was established to compare Doppler ultrasound, volume plethysmography (VPG), and impedance plethysmography (IPG) with ascending venography in detection of deep venous occlusive disease. The Doppler method involved use of a 5.3MHz ultrasound flow probe (Medasonics, Mountain View, CA) sampling the quality of flow in the femoral, popliteal, posterior tibial, anterior tibial and peroneal veins bilaterally. Careful note was made of loss of respiratory variation, impaired augmentation of flow with compression of the limb distal to the flow probe, presence of abnormal collateral veins and reflux with proximal compression as well as absence or change in pitch of flow at each sampling site. VPG was performed using a calf cuff partially inflated to sense changes in venous capacitance during proximal venous occlusion by a thigh cuff and rates of venous outflow after

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Reprint requests to: Department of Surgery, University of Connecticut Health Center, Farmington, CT 06032 (Dr. Donaldson).

thigh cuff release, employing the Pulse Volume Recorder (Model PVR IV, Life Sciences, Inc., Greenwich, CT). The scoring system developed by the manufacturer was utilized, combining the results of plethysmography and a greatly simplified Doppler examination to separate normal from abnormal. IPG was conducted using electrodes placed circumferentially around the calf to measure venous capacitance and outflow, using the Model IPG-200 plethysmograph (Codman & Shurtleff, Inc., Randolph, MA) and the nomogram constructed by Wheeler for scoring results.[6] Ascending venography was performed using Renografin 30 infused into a dorsal foot vein and tourniquets to guide contrast medium into the deep venous system.

All patients who entered the study were referred by their primary physicians to the Non-invasive Vascular Diagnostic Laboratory at the University of Connecticut Health Center because of clinical suspicion of DVT. After obtaining informed consent, a careful history and physical examination of the lower limbs were obtained, followed by Doppler study. VPG and IPG were then both performed, except when presence of a fresh surgical wound, orthopedic appliances, massive leg edema or lack of patient cooperation precluded testing. Venography was obtained on the same day as soon as possible after the non-invasive studies had been completed and interpreted. Performance and reading of venograms was conducted by radiologists without knowledge of the results of the non-invasive tests. Results of all tests were tallied at the end of the project. Findings on non-invasive study were correlated with partial or complete venographic occlusions in (1) any deep vein ("All veins"), and (2) the popliteal, femoral or iliac veins ("AK veins"). In addition, Doppler was scored for presence of DVT in tibial veins ("BK veins"). An insignificant number of patients (four) had isolated DVT in tibial veins, so the plethysmographic tests were not separately reported for BK veins. Statistical significance was determined using the exact test for binomial distributions.

Results

Twenty-three patients agreed to participate in the study. Sixteen patients were studied by bilateral ascending venography, and seven had unilateral study for a total of 39 lower limbs subjected to radiologic diagnosis. All of these limbs underwent Doppler survey, 31 limbs in 17 of the patients were studied by VPG, and 26 limbs in 16 of the patients were studied by IPG.

Sixteen (41%) of the 39 limbs were found to have partial or complete venous occlusions by venography. Correlations between venography and the three non-invasive tests are demonstrated in Table 1. All tests were more accurate in detecting DVT at the popliteal, femoral or iliac level (AK veins) than at the tibial level (BK veins). The Doppler was most accurate at the AK level at 95% of limbs and 96% of patients, followed by IPG and then by VPG. Doppler was only 62% accurate when applied to the BK veins of the 39 limbs tested. Only four limbs had isolated BK DVT without occlusions in the AK veins. IPG was abnormal in one of these limbs (25%) and VPG was normal in all four. False positive limb exams were more common than false negatives for Doppler at all levels of DVT. False negative exams occurred in 14% of AK vein VPG exams with no false positives, whereas 18% of AK vein IPG exams were false positive with no false negatives.

Though overall accuracy of the pooled results of Doppler and IPG was less than for either test alone, certain aspects of the combined test battery were particularly useful. If one or the other or both of these two tests were positive for DVT in any deep vein, only 15% of legs with DVT were missed and no patients with DVT were missed. Equally important, if both tests were negative or both tests were positive, no false negatives or positives occurred for DVT at the AK level. Thus, diagnostic confidence for potentially threatening DVT at the AK level was greatly enhanced by agreement between these two tests.

Discussion

Doppler ultrasonography is an art form in many respects, requiring a high degree of individual skill, adequate time and constant monitoring to maintain excellence. Though many findings are clearly evident even to the novice, there are often subtle differences in flow patterns in main veins and collaterals which can only be clear to an experienced examiner. Recent application of real-time B-mode ultrasound combined with Doppler to the diagnosis of DVT is exciting,[12] as it is possible to detect flow changes and also to actually see thrombus in veins, potentially allowing greater objectivity and accuracy. Unlike Doppler, which must always remain somewhat subjective, plethysmography is a more standardized procedure which produces a hard copy recording and is interpreted from a nomogram.

This small study demonstrates that, in our hands, DVT at or above the level of the popliteal vein can be diagnosed accurately in well over 90% of limbs and patients by the combination of Doppler ultrasound and plethysmography, particularly IPG. Among patients who were tested by both Doppler and IPG, none with DVT in the AK segment escaped detection. Such sensitivity makes it highly unlikely that a patient with significant DVT will remain untreated and at danger of thromboembolism. Furthermore, diagnostic specificity was excellent, with rare false negative limb examinations for DVT in any vein and no false negatives for AK thrombosis when both Doppler and IPG agreed. With such high diagnostic accuracy, these two tests used together have proven to be an effective screening method in our laboratory.

A small incidence of false positives and false negatives, also common to other studies,[8-11] is based on the testing methods themselves. Both Doppler and plethysmography detect changes in venous blood flow, without distinction between various causes of flow change. In addition to DVT, flow can be impaired by external venous compression from a pelvic mass, hematoma, edema, tight underwear or improper positioning of the limb. Systemic conditions causing low cardiac output, elevated central venous pressure, severe decreases in peripheral arterial flow or increased intra-abdominal pressure can cause the IPG to be false positive.[11] If extensive collateral veins have developed around a segment harboring DVT, changes in blood flow may be subtle enough to give rise to a false negative test result. In addition to these weaknesses, Doppler and plethysmography are incapable of demonstrating the difference between chronic venous occlusion or scarring and fresh thrombus. Furthermore, in up to a third of our study limbs, plethysmography could not be employed effectively because of pain from a fresh surgical wound or DVT, extremes of edema or obesity or lack of patient cooperation.

Diagnostic accuracy is inadequate in our hands for DVT in the veins below the level of the popliteal vein. Occlusions in tibial veins will fail to cause any change in venous hemodynamics because of readily available collaterals, and thus plethysmography will be normal until enough tibial veins become occluded to cause reduced segmental flow. Though in the hands of one of us (GRR) and others[4,10] the Doppler probe may be highly accurate for tibial DVT, further experience and study is required in our laboratory to realize the full potential of this technique as applied to BK veins. Fortunately, there is evidence that below knee thrombosis is a relatively benign condition, as opposed to involvement of the popliteal, femoral or iliac veins. In a study of 1074 untreated patients with normal IPG, no fatal pulmonary emboli occurred and the risk of nonfatal embolism was only 1%.[11] An embolus from a tibial vein is likely to be small and of little consequence to all but the most severely compromised patient. Symptomatic post-phlebitic syndrome rarely occurs with isolated disease below the level of the popliteal vein. We agree with Wheeler and others that the risks from tibial DVT are sufficiently small as to approximate the risks of bleeding from treatment of such clots with anticoagulants. If a tibial thrombus is suspected by non-invasive testing or on clinical grounds, it is reasonable to withhold specific therapy in most instances but to maintain surveillance of the patient in the laboratory to assure that the thrombus does not propagate into the popliteal vein. In our experience, such propagation will be reliably heralded by conversion of the IPG to abnormal and clear alterations in the Doppler exam.

Currently at our hospital, we recommend screening all patients suspected of harboring DVT using the combination of Doppler ultrasonography and impedance plethysmography. In most instances, significant DVT can be excluded if both of these tests are negative. If both tests are positive, and there is no obvious potential source of false positivity, the presence of above knee DVT can be safely assumed and therapy initiated without venography. If one test is positive and the other negative, a potential cause of false positivity is present, or a relative contraindication to anticoagulation is present, then confirmatory venography may be helpful. If fibrinolytic or surgical intervention are contemplated, we advise venography in all cases at present. Doppler findings of below knee DVT are relatively unreliable, and we recommend follow-up examination in a few days to detect possible propagation of DVT into the more proximal veins.

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Important Advances in Clinical Medicine

Epitomes of Progress—Physical Medicine and Rehabilitation

The Scientific Board of the California Medical Association presents the following inventory of items of progress in physical medicine and rehabilitation. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers of scholars to stay abreast of these items of progress in physical medicine and rehabilitation that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Physical Medicine and Rehabilitation of the California Medical Association and the summaries were prepared under its direction.

Powered Mobility for Very Young Disabled Children

Gross motor development is severely inhibited in infants and children with thoracic-level myelodysplasia, spinal muscular atrophy, spastic quadriplegic cerebral palsy, arthrogryposis multiplex congenita, four-extremity limb reduction and other profound impairments of the neurologic, skeletal or muscular system.

Until recently, the goal of independent mobility for these disabled children was considered highly desirable but unattainable or possible only in late childhood. Conventional wisdom had dictated that children younger than 5 years were incapable of safely and competently controlling a powered wheelchair and were physically undersized for wheelchairs designed for older children or adolescents.

In a study of 13 severely disabled children with a mean age of 31 months (range 20 to 37 months), Butler and co-workers showed that parents can teach their nonmentally retarded children to drive child-sized powered wheelchairs skillfully. Parental fears that the powered wheelchair would lead to purposeful or accidental bodily injury or property damage were unsubstantiated. Except for one subject, the children used their newly learned skill to explore their homes and, in doing so, accumulated long distances. An important new observation was the development of more spontaneous, self-initiated behavior in speech, play and maternal interaction, whereas movement previously was passive and dependent entirely on parents or older siblings.

Prescribing a powered mobility device for a very young disabled child should be carefully planned. First, the primary care physician or pediatric consultant, such as a physiatrist, should initiate an evaluation by a pediatric occupational or physical therapist. Assessment of the child's behavior, cognition, sitting posture and manual dexterity may lead to specific modifications in seating and control.

Second, the relationship between family and child should be understood before a final decision is made. Supportive parents should have reasonable expectations of their child's present and future development. Comments about motorized wheelchairs should reflect a positive, open attitude and appreciation for normal child development. Smaller sizes, tighter turning radii and greater portability of modern child-sized wheelchairs should allay parental anxieties related to building ramps, buying a van and remodeling the home. Any concern over the family's attention to basic safety, however, should prompt a home visit.

Third, the child should be relatively healthy. The resolution of recurrent skin breakdown, uncontrolled seizures, chronic urinary tract infections and anticipated operations momentarily takes priority over other habilitative endeavors.

Private insurance, charitable foundations, government programs or service organizations often fund generous

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portions of these specialized mobility devices. Bids from two or more reputable, experienced vendors should be encouraged. Where possible, the family and child should be offered choices in detailing the final prescription.

Powered-wheelchair mobility offers very young, physically disabled children an alternative to a restricted, deprived existence at an age when locomotion is critical to normal learning and socialization. Primary care physicians should consider motorized wheelchairs as a safe, affordable and efficient method of habilitating these patients to achieve independent movement.

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Managing Lymphedema With Gradient Pressure—New Devices

Lymphedema, manifested by unilateral or bilateral edema of the extremities, is caused by an abnormality of the lymph vessels or lymph nodes. Increased pressure within the lymph vessels increases the leakage of plasma proteins into the interstitial space with accompanying fluid. The fluid initially causes pitting and is easily reducible, but over time the edema becomes firm and interstitial fibrosis occurs, leading to pseudoverrucal changes. Aside from the devastating effects on cosmesis, the involved extremity is also prone to skin ulcers and recurrent infections; the end result can be osteomyelitis and the loss of a limb.

Treatment in the past has consisted mainly of elevating the affected extremity, administering diuretics, massage and using fitted compressive garments, which can be difficult for an elderly person or one with arthritis to apply. More radical therapies have included sympathetic nerve blocks and surgically removing subcutaneous tissue along with lymph vessel anastomoses. None of these has been entirely satisfactory, with lymphedema frequently recurring to pretreatment levels.

Compressive pumping devices have been used with mixed success; such devices have until recently consisted of a single-celled sleeve that encased the limb and exerted about 40 to 60 mm of mercury pressure over the limb. Although effective for some patients, with others it was noted that appreciable reverse flow occurred to areas of comparatively lower tissue pressure, thereby increasing edema at the most distal and proximal areas of the limb.

The use of two devices that permit the application of graded pressure to different parts of the limb being treated offers more efficient and effective removal of edema. The Wright linear pump is a three-cell pump with a programmable gradient pressure system. The first cell delivers a pressure halfway between the systolic and diastolic pressures of a patient to the most distal part of the limb; the next two cells deliver successively less pressure proximally. At the end of a cycle, all pressures return to atmospheric level. The durations of the on-cycle and the intervals before cell pressurization are programmable by the physician. A second device, the Lympha-Press, also uses multiple compartments, inflating the most distal one first. High pressures are applied (80 to 130 mm of mercury) throughout; however, each more proximal cell is inflated for a decreasing amount of time in sequence (for instance, the foot cell may last for 20 seconds whereas the most proximal thigh cell would last for 2 seconds). The pressure and timing are adjustable to an individual patient's tolerance.

The overall advantage of both devices is the improved centripetal movement of edema fluid with decreased back flow to distal areas. Studies using the Lympha-Press have been done on a population with chronic lymphedema for whom earlier conventional therapies had failed. Results have indicated that treatment time to achieve therapeutic goals is decreased compared with the unicompartmental devices commonly used; biochemical studies indicated that no tissue or muscle damage resulted from the high applied pressure. Although in earlier studies discomfort had been a frequent complaint among patients treated with pressures above physiologic levels, later papers indicated that this is no longer a problem, perhaps due to a shorter duration of application. Results of controlled studies using the Wright linear pump are still pending. Both pumps achieve their maximum effects if used intensively for an initial treatment period followed by much shorter treatments administered three to four times per week indefinitely. If long-term pump treatments are not possible, the use of fitted compression garments is still indicated to help maintain treatment gains.

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Sports Medicine—Muscular Strain

Muscular Strain is a common sports-related injury with the potential to chronically impair performance when sound principles of injury recognition, immediate treatment, rehabilitation and prevention are ignored. Common causal factors include training errors, structural abnormalities and muscular weakness or imbalance. Muscle fatigue due to a sudden change in intensity, duration or frequency of exercise may exceed the limits of adaptation to mechanical stress and result in a new injury or aggravation of a previous injury. Leg length discrepancy, abnormal subtalar joint pronation, tight hamstrings or weak quadriceps following a knee injury may predispose a person to muscular injury from overuse in running sports.

Traditional treatment of acute muscular strain includes ice, compression, elevation and protected range of motion until bleeding and swelling have subsided (usually 24 to 48 hours). Cold therapy immediately following an injury relieves pain and muscle spasm and may decrease the severity of bleeding and inflammatory response. Subacute mobilization facilitated by moist heat, ultrasound, Vapocoolant spray, ice massage or massage is encouraged to prevent progressive weakness, stiffness and pain inhibition of function.

Rehabilitation begins with range-of-motion exercises, isometric strengthening and electrical stimulation until isotonic or isokinetic exercises or both are tolerated through limited to full joint range of motion. Electrical muscle stimulation in conjunction with voluntary exercise speeds recovery by increasing strength responses and decreasing pain inhibition. Strength and endurance exercises continue until normal muscular and functional performance is achieved. Limitations of isotonic exercise are recognized by the popular use of isokinetic machines (Cybex) or variable-resistance machines (hydraulic) that accommodate to strengh demands of the muscle throughout the full range of motion. Cardiovascular fitness is maintained with upper and lower extremity ergometers, swimming, walking or running as appropriate for a given injury.

Chronic muscular strain may respond dramatically to procaine hydrochloride trigger-point injections of tender trigger points or palpable bands followed by aggressive mobilization. Krejci and Koch describe the use of procaine in patients with acute muscle injuries in Eastern European countries for relief of muscle spasm and more rapid return to functional activity.

A greater emphasis on rehabilitation is needed. Pain and immobility from soft tissue injury encourage deficits in muscle strength, endurance and flexibility that predispose to chronic or recurrent injury. Because sports-related injuries occur in persons who want to maintain active lifestyles, our responsibility is to know enough not only to provide quality medical treatment but also to appreciate and share in an athlete's desire to regain maximal function in a minimal amount of time.

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Respirator-Dependent Patients With Duchenne Type Muscular Dystrophy and Amyotrophic Lateral Sclerosis

There is no consensus regarding the use of assisted ventilation in the late stage of progressive neurologic diseases. The medical technology required to prolong life with mechanical ventilation has existed and has been refined for more than 50 years. The ethical implications related to quality of life involved in sustaining patients with progressive diseases are a source of continuing concern. Colbert and Schock recently polled the 240 Muscular Dystrophy Association clinics to ascertain physicians' prescribing patterns with respect to this issue. Of 132 responding centers, 24% did not provide respiratory support systems, 33% routinely did prescribe assisted ventilation and 43% provided them only under specific circumstances. The literature of the past decade contains clinical observations and poignant anecdotes advocating both sides of the issue.

The trend among centers where assisted ventilation is used appears to favor methods that do not require tracheostomy. Negative-pressure ventilators used include the cuirass, plastic wrap systems, rocking bed and the Emerson tank (iron lung). Other forms include the Pneumobelt and instructions in glossopharyngeal breathing. Options for positive pressure devices include either intermittent or constant positive pressure ventilation by mouth. Bulbar weakness frequently precludes this method in later stages. Those patients who have reportedly had the most remarkably extended life spans, up to 22 years, have required positive pressure ventilation via tracheostomy. Improved technology, and more lightweight, portable units have made the home use of positive pressure vetilators more practical.

Many patients have been managed with a combination of methods such as positive pressure breathing by mouth in the daytime and a rocking bed at night, or cuirass plus glossopharyngeal breathing. In an intriguing report by Curran, daytime ventilation measured by gas exchange in patients with Duchenne type (pseudohypertrophic) muscular dystrophy was significantly improved by using an iron lung only at night, thus sparing the respiratory muscles. Patients began to use this method of part-time assisted ventilation at the early signs of respiratory failure and were also supported with vigorous chest physiotherapy. The extended life span was accompanied by the requirement of increasingly longer periods on the ventilator. The possible positive effect of earlier, more aggressive surgical management of scoliosis on respiratory function in this population has yet to be fully examined.

Regardless of the mode of assisted ventilation, decisions about its use are best made electively early in the course of disease rather than later in a crisis of acute respiratory failure. Most articles in the medical literature on this subject imply that the attitudes of physicians and their medical centers weigh heavily in the informed decisions made by patients and families whether or not to choose assisted ventilation. While objective data regarding quality of life are not yet available, physicians are well advised to at least become familiar with the options available to better inform their patients.

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Advances in Orthotics and Mobility Devices for Children With Physical Disability

The prescription of mobility devices for children must take into consideration all aspects of growth and development. During the first three years of life, locomotion and other motor skills are among the primary pathways to learning and socialization. If at all feasible, ambulation is a desirable goal for children even if only for the purpose of exercise.

The traditional bilateral knee-ankle-foot orthosis with pelvic band and hip joint locks allows a tripod gait using upper extremity assistive aids. This gait is unnatural and the energy expended is high. The reciprocation-gait orthosis allows hip motion and provides a more natural and less energy-consuming gait. Also, the orthosis is light, averaging 6 to 7 lbs. The lower extremities, however, must be free of hip and knee flexion contractures with plantigrade feet to accommodate fitting with a reciprocal gait orthosis.

Children with severe limitations in ambulation may find that the vertical wheeler provides a means for safe and rapid mobility. It may be operated either manually with the upper extremities or via a powered mouth-control joystick. An upright posture allows normal eye contact, thus facilitating peer interaction.

After age 1 year, some means of locomotion should be considered for children who cannot move about on their own. The most commonly prescribed mobility device for children with severe physical handicaps is the wheelchair. A variety of wheelchair designs exists, the rear-wheel drive being the most popular. Folding chairs, in particular the light and ultra-lightweight styles, are available. Originally marketed as competitive sports chairs, they are increasing in popularity. Although they are easily transported, some with snap-off wheels, durability is sacrificed and active children may do better with a standard chair. In growing children, proper seating is important to maintain the correct postural alignment. A sling seat should not be used as it places the femoral heads in a position that predisposes to subluxation. Rather, a solid level seat should be the rule.

In children with spasticity and extensor tone predominance, simple positioning to place the head forward and align hips, knees and ankles at 90 or more degrees of flexion can inhibit severe extensor thrust. An abduction pommel with hip flexion and a lap belt are useful to overcome scissoring and hold these children in a more functional and stable posture. An H-harness, lap tray and lateral supports are useful in spastic as well as hypotonic children to provide greater trunk stability.

Children with neuromuscular disease benefit from custom seat inserts. Lumbar extension and pelvic symmetry were suggested to reduce the incidence and severity of scoliosis. In the presence of fixed skeletal deformities, custom seating allows for greater comfort as well.

In severely physically disabled children, a motorized wheelchair with adaptive seating can provide independent mobility. A child between 20 and 39 months of age with normal intelligence can achieve – in less than 12 hours and in one to seven weeks of training – effective and safe operation of this device. The importance of independent mobility in stimulating a child's social, emotional and intellectual growth cannot be overemphasized.

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Sonographic Urodynamics

Urodynamic testing to determine dysfunctional problems of the urinary bladder is now a well-established procedure. A cystometrogram and a simultaneous electromyogram of the periurethral sphincter or simultaneous urethral pressure are necessary for diagnosing detrusor sphincter dyssynergia.

The recent advent of transrectal sonography enables us to view the bladder, bladder neck and urethra during voiding in conjuction with urodynamic studies. The sonographic voiding cystourethrogram is equally as good and sometimes superior to the radiographic voiding cystourethrogram for showing the adequate opening and funneling of the bladder neck and posterior urethra in patients with neuromuscular dysfunction of the bladder. Advantages of the transrectal sonography include the ability to visualize the surrounding soft tissue, enabling detection of benign prostatic hypertrophy, carcinoma or prostatic calculi; there is no radiation to patient or examiner; the ability to continuously monitor pharmacologic manipulation of the bladder neck and posterior urethra during the procedure; the ability to obtain a more accurate recording of residual urine, and the study involves no catheterization, thereby reducing the risk of urinary tract infections.

Combined urodynamics and transrectal sonography have been instrumental in our understanding of neurogenic voiding dysfunction and the role detrusor sphincter dyssynergia plays. Detrusor sphincter dyssynergia is one of the important determinants for upper urinary tract changes in patients with spinal cord injuries. Transrectal sonography has helped to define a hitherto-unrecognized bladder neck obstructive disease associated with detrusor sphincter dyssynergia and intermittent catheterization. We have found a significant posterior bladder neck ledge (0.5 to 2.5 cm) in about 70% of such patients with spinal cord injuries. These ledges were not seen on x-ray films and on cystoscopic examination are seen as a raised bladder neck.

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Cognitive Rehabilitation

Perhaps the most significant recent change in the rehabilitation of neurologic conditions such as stroke and brain trauma has been the emergence of cognitive rehabilitation as a concept and as a major component of treatment programs. This development has signaled a shift away from concentrating on the obvious physical deficits such patients display and towards actively treating the less immediately evident but ultimately often more disabling psychological deficits. Cognitive therapists delineate these individual deficits, which are theoretically innumerable but in practice are generally defined as problems with attention (both concentration and neglect), memory, visuospatial capabilities (right hemisphere), language (left hemisphere) and such "higher order" cognitive abilities as judgment, abstraction and social sensitivity. Obviously damage to the brain interferes to a greater or lesser extent with these cognitive proceses, but the attempt to design specific therapeutic interventions is recent.

A distinction should be made between "cognitive rehabilitation" and "cognitive therapy." The latter derives from clinical psychological and psychiatric fields and essentially is concerned with the interaction of ideas and moods. Habitual thought patterns are felt to create or influence feeling. Cognitive therapy is a psychotherapeutic methodology and is usually applied to persons with depression, with the goal of altering the characteristic ideas of guilt, self-deprecation and so forth of these patients. Cognitive rehabilitation, in contrast, is based on presumed specific basic neuropsychologic deficits previously noted. These deficits are individually identified and usually quantified operationally for each patient, usually by means of neuropsychologic testing. For each defined cognitive deficit, such as inattention or memory dysfunction, specific therapeutic exercises are designed. These exercises require repetitive use of the impaired cognitive system in question, usually in a graded, progressively more demanding sequence. It is presumed these exercises promote recovery of the lost psychological process, which then generalizes to a consequent clinical benefit in overall functioning.

Basic examples of this approach are the recent advocacy of reality orientation groups and memory retraining for patients with stroke, head injuries and psychogeriatric populations. Frequent involvement of confused and disoriented patients in either formal or informal daily "reorienting" activity is reported to be beneficial overall in reducing general disorientation, anxiety and depression. Benefits on general behavior and family distress have also been reported. Graded exercises in various memory tasks, both verbal and visuospatial, have been developed and reported to improve both memory deficits and overall functioning.

Remediation of left hemisphere dysfunction has revolved principally around linguistic and communication issues. Controversy over the benefits of specific therapy for aphasia represents an older subset of the issues of efficacy of cognitive rehabilitation in general. Specific approaches to right hemisphere dysfunction, such as impaired visual scanning, decreased sensory awareness and visuospatial processing, have recently been developed. Higher level, more integrative deficits have also been addressed. Behaviorally based programs for uncooperative, unmotivated and frankly assaultive patients with brain damage have been developed and appear successful, even many years after injury. More subtle deficits of social sensitivity and behavior have also been treated with reported success.

Despite this growing number of reported successful approaches, several important questions remain about cognitive rehabilitation. The magnitude of therapeutic effect is difficult to specify. There is a significant concern over the degree to which improvement in specific elementary psychological deficits, such as basic orientation, visual scanning or mnemonic processes, even if they can be accomplished, generalizes beyond the training environment to produce meaningful overall clinical benefit. Finally, the duration of such effect is unknown. Extended follow-up studies are rare but seem to suggest reversion to baseline. Because of its specificity and minute attention to identifying specifically impaired psychological processes, cognitive rehabilitation is a labor-intensive and therefore expensive modality. Ultimate savings through reduced dependency are theoretically substantial, however. The introduction of microcomputers to do much of the daily repetitious elements of such therapy has the potential to significantly reduce the cost.

The present consensus is that more rigorous study needs to be done to clarify the above issues, but clinical experience would suggest including this element of care in selected cases of central nervous system rehabilitation.

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Wheelchair Sports Medicine

Wheelchair sports medicine involves the assessment of recreational and competitive sport capacities of physically disabled persons, medical classification to allow fair competition among athletes with various types and degrees of disability, the prevention, diagnosis and treatment of athletic injuries and research into the physiology and biomechanics of wheelchair athletics.

As the popularity of sports and fitness training has boomed in the United States and as wheelchairs have evolved into sleek, lightweight, efficient machines, wheelchair athletes have grown in importance and acceptance. Men, women and children with varying degrees of disability have become involved in a wide spectrum of individual and team sports including basketball, volleyball, fencing, shotput, discus, javelin, archery, slalom, wheelchair racing, marathon racing and even mountain climbing. Tennis, table tennis and bowling have become popular as sports in which disabled and able-bodied persons can play together.

The physiologic benefits of participating in sports are specific to the type of training undertaken. Wheelchair athletes can show a significant, measurable increase in endurance and cardiorespiratory performance, as well as improved skeletal muscle strength, speed, coordination, balance and flexibility. Possible psychological benefits include a positive impact on sense of competence, self-esteem, self-reliance and leadership.

Wheelchair athletes have insisted on departing as little as possible from the original version of each sport. In wheelchair basketball, for example, the baskets are not lowered. Interestingly, the wheelchair has assumed status and significance similar to the polo player's horse or the hockey player's ice skates.

Medical classification is done according to National Wheelchair Athletic Association and National Wheelchair Basketball Association rules, which require that muscle strength, sensation, spasticity, balance and deformities be assessed. As with the categorization of competitors by weight in able-bodied sports such as boxing and weightlifting, the opportunity to compete on equal terms with others is ensured in wheelchair sports by quantifying the degree of disability. This permits persons with a similar severity of disability to compete against each other.

The most prevalent injuries sustained by wheelchair athletes are soft tissue injuries, blisters and skin lacerations or abrasions. Major injuries such as fractures or trauma leading to further permanent disability are rare. Soft tissue injuries occur most commonly at shoulders, elbows, wrists and hands. These include muscle pulls, strains, sprains, bursitis and tendinitis. Many of these injuries are recurrent. They are caused by tearing and overstretching of ligaments during falls or physical contact, by chronic overuse of muscles and tendons and by overexertion without proper warmup. Blisters of the hand and fingers are also quite common and are caused by traction or irritation of skin in contact with the wheelchair rim or tire. The skin exposed at the top of the seat post on the back of the wheelchair may also be at risk for blisters. Abrasions and lacerations of the fingers, thumbs and arms may be caused by contact with brakes or sharp edges of the wheelchair, by contact with the larger tires of track chairs or by fingers being trapped between wheels as, for example, during basketball.

Decubitus ulcers, primarily a problem among athletes with spinal cord injuries, are due to shear forces and pressure over the buttocks and sacrum. Sports wheelchairs that are designed with the knees higher than the buttocks may also contribute to the problem by increasing pressure over the sacrum and ischial tuberosities. Sweat and moisture combine with shear forces to complicate the problem.

Temperature regulation disorders are caused by an inability to respond to changes in heat or cold, especially in persons with quadriplegia from spinal cord injuries.

It is important that athletic performance, which is well above average functional performance, be considered as the goal in diagnosing and treating the soft tissue injuries of the disabled athlete. Conditioning and strengthening after an injury must go well beyond the strength, power and endurance required for the performance of ordinary activities of daily life.

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Functional Electrical Stimulation

In 400 BC Greek physicians recommended using the electric torpedo fish (family Torpedinidae) as a treatment for paralysis. In 1791 Galvani linked electrical stimulation to muscle contraction. Electrical stimulation was enthusiastically promoted in the 19th century for a variety of ailments, firmly establishing this modality in the pantheon of quackery.

Advances in electronics and neuromuscular physiology engendered more realistic applications of electrical stimulation. It is widely used as an adjunct to physical therapy (sometimes this specific clinical use is equated with all of functional electrical stimulation) and as a pain treatment modality (transcutaneous nerve stimulation). In 1961 Lieberson coined the term "functional electrotherapy" for electrical stimulation used in place of an ankle-foot orthosis for hemiplegic footdrop. Useful movement of the ankle dorsiflexors was produced by heel-switch gated stimulation of the peroneal nerve. Improvements in reliability, size, materials and computerization have led to portable and even implantable systems of remarkable sophistication. Notable are those devices for phrenic nerve stimulation, sacral root stimulation for micturition and peripheral nerve or motor point stimulation of upper extremities for hand function or the lower extremities for standing and ambulation. Strategies of sensory feedback are being investigated in some patients to give a more physiologic approximation of function.

The clinical application of these systems requires an experienced team including physicians, therapists and technicians. A fairly sophisticated level of patient and family cooperation is essential. The high current requirement and loss of neurotrophic factors in denervation (lower motor neuron paralysis) limit electrical stimulation to conditions where the motor units are intact (upper motor neuron paralysis). Extensive conditioning programs, in addition to standard rehabilitation, are needed to strengthen atrophic muscles and improve fatigue resistance of electrically stimulated muscles. This "functional electrical exercise" may have physiologic benefits in itself.

Media attention has tended to obscure the fact that these systems are electrical orthoses and do not cure underlying disease. They are appropriate only when the lower motor neuron is intact and may adversely affect recovery in cases of incomplete lower motor neuron disease. Despite this, functional electrical stimulation remains a rapidly evolving area of rehabilitation that in the near future may provide significant functional options for the severely disabled.

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Vocational Potential in Multiple Sclerosis

Multiple sclerosis affects an estimated 123,000 adults in the United States, and 90% have the onset of their disease in their vocational prime, between the ages of 15 and 50. Several studies have shown an unusually high level of educational accomplishment in this population, with almost half in one study having some postsecondary education. Yet, the incidence of unemployment in the multiple sclerosis population is extremely high, and the cost of this unemployment to society is considerable.

In a study done in the United States in 1981, less than 20% of patients with multiple sclerosis were still employed 20 years after diagnosis. In a study done in West Germany in 1965, nearly a third of the patients studied were still employed 20 years after diagnosis. Yet, an Israeli study from 1981 found that more than 50% of persons with multiple sclerosis continued to work, and the study population included the entire known group of persons with this disorder in Israel at that time. The reasons for the significant national differences in percentages of employed persons with multiple sclerosis are not known. There are substantial differences between American, Israeli and German cultures, but they share enough in common to warrant study to achieve the best possible level of employment, especially with the US rate falling more than 30% short of the highest rate found.

Many problems may create vocational difficulties for a person with multiple sclerosis. Visual problems, ataxia, fatigue, mobility problems, urinary urgency and frequency and cognitive problems all can be severely disabling on the job and cause a need for substantial job modification.

The frequency of cognitive problems in persons with multiple sclerosis is high. More than 50% of patients in one recent study tested in the impaired range despite a mean diagnosed length of illness of less than seven years. Of the cognitive deficits seen, many are of considerable vocational significance. They include many frontal lobe function problems such as the loss of abstract conceptualizing skills, short-term memory and new learning ability, as well as impaired concentration and reduced insight. These problems often are clinically silent. Failure to function cognitively may lead a person to leave a job but transfer the blame to "physical difficulty." A thorough evaluation of cognitive function is useful in assessing ability and disability and in planning a vocational rehabilitative strategy. Counseling may play a very helpful role in learning to cope with cognitive disability.

Urologic problems are frequently mentioned as a problem on a job. The commonest problems reported have been urgency and frequency. Medical management of persons with neurologically impaired bladders can greatly assist in these difficulties.

The most rapid assistance with maintenance of vocational function at the moment may be through patient-physician interaction. Formal referral to vocational rehabilitation agencies may be necessary when a person is already unemployed. The appropriate medical, psychological and rehabilitative interventions may greatly facilitate the process of job placement. A proactive step in the direction of vocational counseling may make a substantial difference in job retention, which is certainly the easiest form of vocational rehabilitation.

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Orthostatic Hypotension and Cardiopulmonary Response to Compressive Garments After Spinal Cord Injury

Huang and co-workers have described the effects of a pneumatic abdominal corset and pneumatic leg splints inflated to 35 mm of mercury and 65 mm of mercury, respectively, in maintaining cardiopulmonary responses during a postural change. The corset was more effective than leg splints in limiting the systolic and diatolic drop in pressures, and both devices were more effective than no device in maintaining blood pressure and limiting a heart rate increase. Oxygen consumption and energy expenditure increased with the use of compressive devices. With their use, therapeutic modalities and postural challenge may be initiated earlier in the rehabilitation process.

Orthostatic hypotension is common in the early stages after spinal cord injury. When lesions are above the sympathetic outflow at T-5 to T-8, there is loss of reflex vasoconstriction and pooling of blood in the extremities. A postural change in a patient with quadriplegia or high-level paraplegia results in tachycardia due to a vagolytic response via the carotid body, but this is inadequate to maintain blood pressure in the presence of blood pooling. The symptoms of lightheadedness and dizziness signal the need either for returning to a supine position with the legs elevated or for an assisted tilting back of the wheelchair. Fainting can occur in 100% of persons with complete C-4 or C-5 lesions, with a mean onset in less than two minutes.

Preventive measures can minimize the dramatic blood pressure drop during early mobilization after an injury. The average resting blood pressure of 90/60 mm of mercury in a quadriplegic patient leaves a small margin for change. Full-length elastic stockings and an abdominal binder limit venous and splanchnic blood pooling. A gradual position change from supine to sitting with eventual dangling of the legs may require 30 minutes or longer. Blood pressure monitoring is most easily accomplished with an automated sphygmomanometer. When the patient is finally transferred to a wheelchair, elevating leg rests and an assistant to provide wheelchair tilt backs is essential. Some spinal cord injury centers use progressive "training" on a tilt table, but this has never been adequately documented as effective in speeding the mobilization process. If patients remain symptomatic, one should prescribe a liberal salt and fluid intake. Ephedrine sulfate, 25 to 30 mg one to four times a day, acts as sympathomimetic agent and, when used, should be given 30 minutes before positional changes. A patient should be watched for an excessive blood pressure increase on returning to the supine position. Fludrocortisone acetate (Florinef), 0.1 mg to 0.2 mg given twice a day, is the next drug of choice due to its mineralocorticoid effect.

Orthostatic hypotension in most persons resolves within several months of injury. Episodic hypertension and autonomic dysreflexia may appear as sympathetic reflexes return. The unusual onset of symptomatic orthostatic hypotension late after injury should alert a physician to consider such problems as posttraumatic cystic myelopathy.

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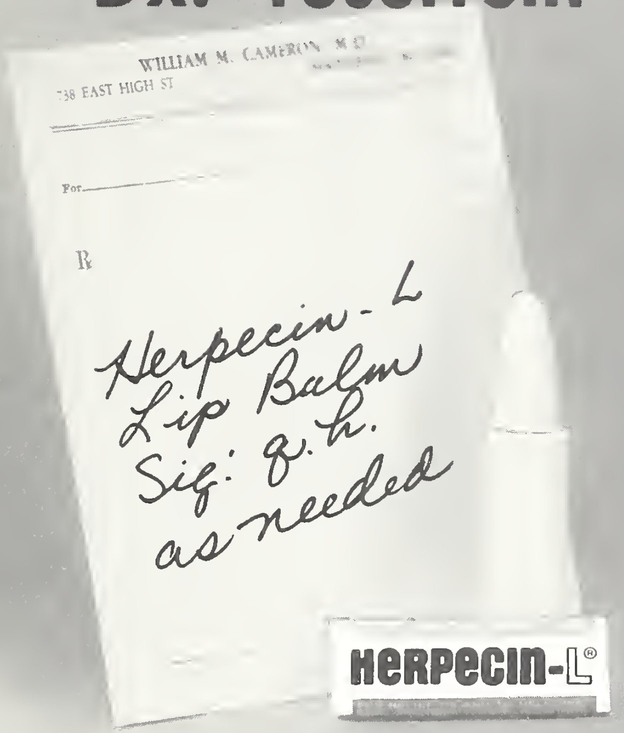

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An open letter to

The present malpractice insurance situation in Connecticut raises some serious questions which must be clarified.

Some observers of malpractice insurers have over-simplified their view. These same observers view assets as generating sizeable investment income; "more than enough" to pay all claim settlements and expenses, leading to further observations of windfall profits, gouging, or some other more notable terms.

Investment income is the interest earned on premiums set aside to pay future claims. It became a significant factor in the malpractice business during the mid to late 1970's when interest rates were so high. The prospect of high investment income attracted new competitors to this line of business.

Unfortunately, during this period a substantial increase in claim costs also was taking place. As interest rates started to decline, insurers began to discover that their costs had jumped considerably and income from premiums and investments was not adequate to make up for the higher claim costs.

The forgotten item, many times, is the fact that financial liability accepted by a malpractice insurer for malpractice claims runs for *many years* after premium has been collected.

When any business loses money, there are two basic options: raise prices, or quit the business. That is exactly what is happening to the medical malpractice insurance business. Some insurers have been forced to increase premiums and even reduce or restrict coverage. Others have stopped selling malpractice insurance altogether. Industry sources have identified as many as 29 insurance companies that either have totally or selectively withdrawn from the medical malpractice marketplace.

Interestingly, the only new writers of malpractice insurance are physician-owned insurance companies, called *captives*, established only within the last decade. Until recently these captives had not had to deal with the tremendous financial risks associated with this line because they had not been in existence long enough. Recent industry reports indicate that a number of captives now are beginning to see the same adverse claims experience as commercial insurers... and just how complicated and risky this business is.

Like many commercial insurers, many captives have had to begin using their surplus funds to compensate for the inadequacy of their premium structure in previous years. Unlike commercial carriers, the surplus accumulated by these captives may be limited, as was pointed out recently to The National Association of Insurance Commissioners by the Alliance of American Insurers while addressing the pending solvency problems of many medical malpractice insurers.

Insurers often *do* use surplus funds to pay claims when premium and investment income are exhausted, but it is irresponsible to *plan* to use surplus funds to pay claims.

Connecticut physicians:

Statutory requirements set up by insurance regulators require that insurance companies establish "surplus" funds to make sure there is enough money to pay claims. Surplus is defined as the amount by which assets *exceed* liabilities.

For more risky insurance lines — like malpractice — more surplus is necessary. Furthermore, as premium and risk exposure grow, surplus must also grow in order to maintain this same level of protection for policyholders. But surplus can only grow from profit on the business or investment income on surplus.

An insurance company must have a strong surplus position to meet its financial obligations to policyholders. If a malpractice line shows accelerated claim costs and more frequent claims than were anticipated, premium and investment income will not be adequate.

A continued depletion of surplus funds is a sure sign of serious problems for the insurance company, especially given the risk of even higher claim costs coming tomorrow, next week, or even ten years from now. No insurer can fund deficiencies out of surplus indefinitely.

Are rates too high? Not considering the most recent experiences of the CNA Insurance Company, a major underwriter of malpractice insurance for Connecticut physicians. CNA's rates show a prudent and long-term approach to the marketplace.

Could they be lower? Not without seriously undermining the financial integrity of the CNA medical malpractice insurance program in Connecticut.

To remain in the market for the long-term, CNA must remain a financially strong company. Implementing rate increases is but one part of dealing with the complex problem of medical malpractice insurance. Solving this problem will require the sustained efforts of physicians, legislators and insurers working together to find equitable solutions. That will take time.

Until then, CNA will continue to provide a responsible, financially strong malpractice insurance program for Connecticut physicians, through good times and bad. CNA made a commitment to the Connecticut marketplace to provide insurance protection for medical professionals in the state. CNA intends to stand by this commitment.

Respectfully submitted,

Joseph S. Flynn
Vice President

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The President's Page

Medicine in the Government

Governmental intervention in the practice of medicine is disruptive to the physician-patient relationship and impacts adversely on the quality of care. Anyone with any degree of intelligence knows this, and that is why we must not stop trying to counteract it. Here are some suggestions to accomplish this.

The statewide courtesy card program for Medicare patients is one program all physicians should support. For those of you who may not be aware of the program, it is one in which the Medicare population, based on a demonstrated need, will be issued a courtesy card. When this card is presented, the participating physician providing the medical care will automatically accept assignment. We will have to educate the public that, contrary to popular belief, this does not mean the waiver of the deductible coinsurance. It is *illegal* not to make an attempt to collect this coinsurance, according to federal guidelines.

We all know that state legislatures often act in ways which are mysterious to the general public. In many instances, we, the observers, simply do not understand the system. In others, we have trouble understanding the rationale behind certain legislative initiatives. This year, a bill submitted to the Connecticut General Assembly tried to make licensure to practice medicine dependent on the practitioner accepting Medicare assignment if he or she treated Medicare patients. While this would appear to be blatently unconstitutional, the Massachusetts court system did not find it so. The issue in our neighboring state is now on appeal to a higher court. We will watch the results with great interest.

In Connecticut, the proposal was defeated in committee with the proviso that a study committee be set up to look at the question and report back to the legislature next year. So, the issue is certainly not dead. If we are to defeat this legislation, it will require great effort on our part. We will have to show the legislature that we do have an interest in the elderly population. I know we do, and you know we do, but we will have to make it a more visible concern to those who pass our laws.

I would like to recommend a new program to enlist the elderly on our side in the fight to protect and preserve their right to quality health care. The Connecticut State Medical Society, with the co-operation of its members, should mount a vigorous campaign to align the elderly with us. After all, we do have much in common. They are the target of hare-brained, bureaucratic programs in which we are forced to participate and for which we, in many cases, take the blame. With programs similar to the courtesy card and a variety of educational seminars on health and nutritional topics, we should be able to convince our senior citizens of our sincere desire to protect their health and wellbeing.

Many have said that the medical profession only gets exercised over issues which impact on medical economics. Once again, you know and I know that this is simply not the case. Our record of defending quality of care for *all* segments of our society—not only senior citizens—is one of which we can be justly proud. Now it seems as if we are being challenged once again, and we better not drop the ball. To do so would be catastrophic for us and our Medicare patients.

Joseph C. Czarsty, M.D.
President

Reflections on Medicine

A Half Century of Progress

ROBERT U. MASSEY, M.D.

When does journalism stop and history begin? Last month, last year, before Watergate, or World War II? Or is history only a literary restoration of that past which precedes living memory?

The history of medicine always seemed to start with Hippocrates, but even he, or a contemporary, had written a work called *Ancient Medicine,* not exactly an historical piece, but one which presupposed that our art even then (420-430 B.C.?) was old, as surely it was.

Yet modern medicine, the medicine with which we are familiar, dates back to Robert Koch and anthrax in 1876, or maybe W.G.T. Morton and ether on October 16, 1846, or perhaps William Harvey and *De motu cordis* in 1628. Whose favorite legend or hero begins our era? Koch, Pasteur, and Lister probably come closest. Few would deny, however, that the exponential growth of medicine as the newest science is little more than a century old; if that is granted, then *Connecticut Medicine* has been witness to half of it.

1936 was a felicitous year to begin a journal. The darkest days of the Great Depression were over; the horrors of the Holocaust and the destruction of World War II were foreseen by some, but mercifully or unfortunately, invisible to most. The optimism of the Progressive Era yet lingered and with it the faith that democracy, science, good will, and hard work would continue to improve the human condition.

Medical progress was an undeniable symbol of that cheerful hope; those of us old enough to remember those days believe we can recall that good feeling. Perhaps, but we need always to be on guard: our memories protect us by being more selective than we know; almost any fifty-year stretch of time looks golden at its beginning. Maybe that is why there has always been a Golden Age from which, our old men tell us, we have declined, and why myths of the beginning almost always describe a place like Eden.

But look! Sulfanilamide (Prontosil) was first used at the Bridgeport Hospital (reprinted in this number) in December, 1936. Dr. Daniel C. Patterson, President of the Connecticut State Medical Society, reported eight cases in detail, but told of being "favorably impressed" by results in over one hundred; then he lets down his scientific reserve: "Its action in some cases has been most spectacular, and seemed alone responsible for saving the patients' lives."

I recall reading the account of this new drug in the medicine section of *Time,* then asking for some additional information about sulfanilamide from our family doctor. I used it all for a report in my high school English composition class and got an A+! I too had written with some feeling; one of my friends had died the year before from "blood poisoning" which followed a minor injury. "Death can enter through a pinprick," I remember hearing. A neighbor's eight-year-old daughter had died several years before from "spinal meningitis," and I recalled a classmate in the fourth grade who never returned, and we were told later it had been spinal meningitis. When I was ten years old I had been treated for lobar pneumonia by our homepathic physician (who had only lukewarm homeopathic convictions, I came later to know) with very dilute potassium iodide. When my parents asked about the outcome, his response was, "You know how pneumonia is."

Suddenly having the means, or the almost certain hope, of controlling bacterial infections changed not only medicine but world history. As in all technologic advance, there were losses and gains; stopping pneumonia in its tracks when life should be coming to a close is often no boon; maybe our enemies planned their World War II campaigns more recklessly knowing that sulfonamides and later penicillin were available. Our campaign in New Guinea and the Solomons was successful in part because of sulfaquanidine. And of course there is the population problem.

But only physicians who live their lives one patient at a time can know that saving a young life threatened by streptococcal or meningococcal disease is the very best thing in the world to do. The polyglot crowd who are trying to "cut medicine down to its size" and who ask "why those doctors think they are different from everyone else" cannot match that one. Do they know that we have only started?

We need to be careful; it is easy for physicians to fall into the mortal sin of *superbia,* and our arrogance has not always gone unobserved. But after so much talk of doom and crepe hanging recently, a little horn blowing on the occasion of a Golden Jubilee may be forgiven, even by our tiresome detractors, who, like the poor, are always with us.

ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, Ct.

We know your time is valuable.

That's why we're asking you to take the time to watch a valuable 10-part series on Public Television this Fall entitled **"Managing our Miracles: Health Care in America."**

Produced by Columbia University Seminars on Media and Society, "Managing our Miracles: Health Care in America" will be broadcast on Connecticut Public Television on Tuesday evenings from 9-10 P.M. Each week, the series will bring together panels of nationally-known leaders and decision-makers to debate many of the medical, legal, and ethical problems which you, as a physician, confront every day. A distinguished moderator will lead the panelists through hypothetical case studies, presenting a balanced and thoughtful discussion of issues which can neither be simplistically answered nor safely ignored.

We urge you to watch "Managing our Miracles: Health Care in America." Not to hear easy answers, but to discover a way in which we all can work together to find workable solutions.

Programs may be viewed on Connecticut Public Television Channels 12, 24, 49, 53, 65 on Tuesday evenings at 9:00 P.M. Please check your local program guide for last-minute scheduling changes.

October 7: "Truth and Confidences." An exploration of the relationship between doctor and physician, moderated by Harvard Law School Professor Arthur R. Miller, and featuring panelists Supreme Court Justice Harry Blackmun; Dr. Willard Gaylin, President of the Hastings Center; philosopher Sissela Bok; Rhode Island Attorney General Arlene Violet; Dennis Campbell, Dean of the Duke University Divinity School.

October 7 (10 P.M.): **"Transplants: Second Chance at Life."** An examination of the harvesting and distribution of human organs, moderated by Yale University President Benno Schmidt and featuring panelists Dr. Michael DeBakey; Senator Albert Gore of Tennessee; Surgeon General C. Everett Koop; ABC Medical Correspondent George Strait; New England Journal of Medicine Editor Dr. Arnold Relman; nationally-syndicated columnist Ellen Goodman.

October 14: "The Human Heart Machine." A discussion of the risks and benefits of the artificial heart, moderated by Benno Schmidt and featuring panelists Dr. William DeVries; Dr. Robert Jarvik; Senator Albert Gore.

October 21: "Malpractice." A discussion of what malpractice and the malpractice crisis means to doctors and their patients, moderated by Harvard Law Professor Charles Nesson and featuring panelists Justice Harry Blackmun; Dr. James Todd, Vice President of the American Medical Association; Surgeon General C. Everett Koop; "Nightline" host Ted Koppel.

October 28: "AIDS: In Search of a Miracle." An examination of some of the vital questions presented by this frightening health crisis, moderated by Harvard Professor Arthur Miller and featuring panelists New York Mayor Ed Koch; Dr. Mathilde Krim, co-chair of the American Foundation for AIDS Research; Georgia Congressman Newt Gingrich; Dr. James Chin, Chief of Infectious Diseases at the California Department of Health; CBS Correspondent Susan Spencer.

November 4: "Technology Rocks the Cradle." A discussion of the issues surrounding pre-natal testing and the advances in neonatology, moderated by Columbia Law Professor Harold Edgar, and featuring panelists John Cardinal Krol; Surgeon General C. Everett Koop; CBS Correspondent Ed Bradley; Massachusetts Congressman Barney Frank.

November 11: "The Smoking Dilemma." A discussion about who's responsible for regulating smoking in public and whether or not tobacco advertising should be banned completely, moderated by Professor Charles Nesson and featuring panelists Surgeon General C. Everett Koop; R.J. Reynolds Tobacco Company Counsel John Strauch; California Congressman Henry Waxman; Eugene Patterson, Chairman of the St. Petersburg Times; Columnist Ellen Goodman.

November 18: "Battered Child, Battered Trust." A second examination of the patient/physician relationship, this time as it relates to its impact upon the growing number of abused children in our country, moderated by Professor Arthur Miller and featuring panelists Justice Harry Blackmun; Dr. William Gaylin of the Hastings Center; Dr. Arnold Relman of the New England Journal of Medicine; Philosopher Sissela Bok; Rhode Island Attorney General Arlene Violet.

November 25: "The Business of Medicine." A discussion of what the many changes in health care delivery may mean to someone who needs treatment, moderated by Columbia Law Professor Lewis Kaden and featuring panelists Joseph Califano, former Secretary of Health, Education and Welfare; California Congressman Henry Waxman; David Jones, Chairman of Humana Hospitals; Dr. Arnold Relman of the New England Journal of Medicine; Economist Lester Thurow; Pennsylvania Governor Dick Thornburgh.

December 2: "Final Choices." A discussion of health care for the elderly and the terminally ill, moderated by Benno Schmidt and featuring panelists Justice Harry Blackmun; Surgeon General C. Everett Koop; Colorado Governor Richard Lamm; ABC's Ted Koppel.

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Connecticut Medicine

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Editorials

A Lesson of Fifty Years

The most important change affecting the practice of medicine has been an evolution of public expectation regarding medical care. In 1936 the public tended to regard medical services, especially expensive forms of therapy, as an opportunity for those who could afford the cost. Many of those who could not afford to pay for it could still obtain it, but the luxuries of medical care and regular treatment or examination were less likely to be available. Whole sections of our national community lacked adequate medical care. This sense that availability was related to one's own success or failure in the acquirement of wealth, however, was softened by the middle of the Depression under the intervention of the federal government to provide the basic needs of persons and families. The depth of the economic plunge was far beyond the resources of voluntary programs, and dramatic federal steps seemed appropriate. That reformers would want to provide adequate medical care for everyone, regardless of ability to pay, is not surprising. But, as we have found, the provision of medical services under some general governmental scheme is fraught with difficulties.

The medical profession generally opposed the shift of practice from a fee-for-service pattern to one in which the government or some other entity would oversee and make the final decisions on patient care. Reasons for concern included the fear of losing a system with which every practitioner was familiar, regimentation in a profession which had been individualistic for generations, as well as the protection of each patient's best interests.

The worries of many practitioners were relieved by the establishment of pre-paid insurance programs such as Blue Cross and Blue Shield. In the 1960s the federal government, again addressing the problem of poverty, sought to make health care available to those who could not afford an insurance program. Health care was presented as a citizen's right. This attitude toward medical care, including the most expensive forms of treatment, has had interesting results. When the decision for the amount of resources to apply to a particular ill person is taken away from negotiation between patient and physician and made, ultimately, by an elected assembly, cost becomes difficult to curb. This problem is compounded by the existence of astronomically expensive, elaborate, sophisticated and care-intensive procedures such as kidney dialysis. The federal government has found it difficult to say who would not receive such high cost care. Elected officials can not afford—in a political sense—to suggest that any life is expendable.

Physicians are currently in the middle as government health programs endanger the fiscal security of the nation. Controls are applied to physicians' judgments now less as part of a philosophy than as an emergency measure. The irony is that the advance of medicine has created new types of treatment at very high cost, but these same treatments often extend life only briefly and at times in circumstances of diminished quality.

Physicians have a unique role in this crisis of health services and cost. Their working conditions, conflicting pressures regarding therapeutic decisions, and the overall medical care of their patients are all subjects about which physicians have valuable and special knowledge. A lesson to be learned after a review of the last half-century of medical practice is that physicians must carve out a significant portion of their time and work within professional organizations. Only by strenuous effort will the viewpoint of practicing physicians be conveyed to legislators and the public, two groups who should have such information when making profound decisions defining the role and circumstances of the medical profession. We memorialize the pioneers associated with *Connecticut Medicine*, physicians such as Doctors Barker, Blumer and Weld, who saw the importance of meeting and understanding the concerns of the larger society with information obtainable only from the profession. The challenges prevailing during the next fifty years will require new generations of informed medical leaders drawn from practicing physicians.

David F. Musto, M.D.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself responsible for statements made by any contributor.

A Time Capsule That Is Not Hard to Swallow

Highlights from the early *Journal of the Connecticut State Medical Society*

Perhaps we have all had the nostalgic opportunity of looking at an old newspaper or magazine while unpacking boxes or crates which were put away long ago. Stealing a look back in time as to what the current events of the day were seems very interesting to most of us, I believe. Although a look backward in time of only 50 years may not seem significant, in light of our technologic knowledge and medical advances, it does give us some type of gauge to show the tremendous strides that have been made in medicine and the relation of medicine to the community, as well as the organizational status of our physicians. I have abstracted a few comments therefore from our Journal of 50 years ago which will hopefully prove to be of interest and possibly even amusement.

Some of these articles and items listed are of interest because of their perceptiveness about things to come and others of interest because of their antiquity and outdated status. Although malpractice and professional liability were a very small problem at the time, an interesting article was devoted to medical expert testimony. In a time when we are still considering who is to be identified as a true "expert witness" this article was of interest not only then but rereading it now 50 years later. Dr. Charles Larkin of Waterbury had interesting comments regarding the formation of the Tumor Registry at that time and the percentages of different malignancies noted in a rough statistical survey taken then. A strong case is made, even for those days, for getting an annual physical examination and enlisting the co-operation of physicians in regard to reporting tumors, etc.

The matter of employment of a full-time executive secretary for the Society was given a great deal of comment. It was felt that a layman would probably be more amenable to guidance and suggestions from the regulating committee than a physician in this job. He may not have the temptation to "assume too great responsibility with medical matters without medical consultation." It concludes that the "chance of getting an able person for this position at the salary contemplated are better with a layman." A strong move was made 50 years ago to have the Connecticut State Medical Society office located permanently in Hartford. Several interesting comments for and against this position are mentioned in this Journal of many years ago.

Some of the financial matters are of interest. From a time long before inflation and certainly at a time when the depression was beginning to climb out from its lower depths, the executive secretary's salary was $4,000, total allotment to include office rent, stenographers, office equipment, etc. ran to $12,000. Dues for the year of 1936 were placed at $5.00 (nonetheless, several members were dropped for nonpayment of dues and these are also listed). Dr. Creighton Barker was the treasurer, and an excellent financial report of the status of the Society was given in this August 1936 issue. This August Journal is replete with the activities of many of the committees (most of which are still in existence). Some unusual reports included the newly formed Social Security funds and how they were to be placed and used by public health facilities in Connecticut. An interesting committee dealt with the narcotics problem. This committee on narcotics dealt with some of the same matters dealt with now in regard to medical control of the use of narcotics, an interesting side comment being that "there is a general feeling by informed observers that legislation prohibiting use of barbiturates except on prescription would be premature. This matter should be kept under advisement." Apparently times were improving economically since the Connecticut State Medical Society committee on emergency unemployment medical relief was felt to discharge its duty and was disbanded. A lengthy report was given by the delegate to the AMA. There was an increase in the enrollment of the AMA to 103,241 which was an increase of 4,000 from the previous year. The fellowship dues of $7.00 included the subscription to the Journal as well. Even 50 years later, many members who were active in those days have names which are still remembered by some of us. This includes Dr. Samuel Harvey (who reported on the Committee of Medical Expert Testimony); Dr. Edward Ottenheimer of Willimantic, who discussed the matter of ethical status of physicians' telephone listings; Dr. Stanley Weld who reported on Emergency Unemployment Medical Relief; and Dr. James Gold on the Committee of Medical Economics. Other names that are prominent throughout the reporting of the activities of the Society included those of Dr. Carl Johnson, Dr. Herbert Thoms, Dr. Noah Creadick, Dr. Milton C. Winternitz and Dr. Bayne-Jones of Yale. Public health matters were discussed in relationship to the problems of their times by Dr. Stanley Osborne and Dr. I. Linde. We can look back at a time when polio was a nightmare that faced medicine and the populace every summer. A great deal of committee action dealt with the problems related to its diagnosis and treatment at that time.

It is interesting to glance through the medical advertisements in those days. These seem to offer the greatest contrast to what we are now used to seeing. Although trusses, belts and elastic stockings still have some definite place, apparently hernia repairs are more common now than the life-long use of trusses. Advertisements from Eli Lilly professing the superiority of their "made from beef pancreas" insulin was interesting. The fact that it was highly purified, stable, free from pigmentary impurities and proteinous reaction producing substances was interesting also. The advantages of goat milk as the ideal food and the use of antiphlogistine tablets were noted to enhance osmosis in capillaries. Many ads dealt with the superiority of cigarettes. Phillip Morris invited you to send in an attached form for which you would personally receive two packs of Phillip Morris cigarettes, English blend, with the understanding that "the dietholineglucol used would be less irritating than those in which glycerine is used as the hygroscopic agent." A Chesterfield ad was also noted and other matters which are now considered out of fashion for advertising in medical journals.

The overview of what was happening 50 years ago is interesting more because of the fact that they faced problems much in the same way that we face them nowadays. Most assuredly, 50 years from now, medicine will look back at our attempts as being very puerile and possibly lacking in scientific basis. In looking over such old journals, the thought seems to come through that the doctors were truly devoted toward a good outcome for their patients. The matters presented at their 12th clinical congress further speak strongly to this point. The regular use of antibiotics, adequate anesthesia and much of the available technology now present today gives us greater reason to admire what was done 50 years ago without such advances. The clinical observations of the patient and diagnostic acumen carried our predecessors a long way down the road toward proper care of the patient without the large degree of technology now present. Rather than find any basis for ridicule of these doctors of 50 years ago, I think that it is easy to find a basis for great admiration for such devoted physicians.

I hope, therefore, that our readership will find time to look at some of those characteristic articles, reprinted in this issue of the Journal. At a time when antibiotic therapy was unknown and chemotherapy was coming on the scene, the article on Prontosil should be of interest. At a time when cesarean section rates are higher (and maternal and fetal mortality much lower), a look back to the problems facing the agonizing decisions made regarding cesarean sections 50 years ago are presented. The matter of the effects of the oncoming era of specialization are noted in the editorial and might create much interest in the reader and is submitted for your consideration. Dr. Weld's article provides a capsule history of the Journal to 1958.

Stewart J. Petrie, M.D.
Editor Pro tem

Lister's Great Discovery

A professor of history once told me that we are interested in history because we are trying to figure out who we are by digging up our ancestors. Perhaps, but physicians have had a special devotion to the history of medicine because that history is often dramatic, almost always a good story, and helps to account for their consuming attachment to their profession. Howard A. Kelly, then Professor Emeritus of Gynecology at Johns Hopkins, addressed the Connecticut State Medical Society at its Annual Meeting in May, 1937. He gave an extensive account of the early days of antiseptic surgery more than half a century before. That was *his* history and his hero had been Lord Lister. Here is a brief excerpt from his delightful, rambling talk as it was published in *Connecticut Medicine*, November, 1937:

> "My first experience with "antiseptic" surgery occurred in connection with a good surgeon, in the Episcopal Hospital of Philadelphia where I was resident. Attempting an antiseptic operation on a strangulated hernia, he cut through the wall, and the bowels popped out over the bed. It was antiseptic surgery, just the same. The idea our predecessors had was that there was some kind of drug you used which worked a sort of magic. The idea which was always in Lister's mind, with whatever change might come—the great principle of disinfection through killing the germs or preventing their entrance—didn't get into the heads of the older men, even such splendid men as Agnew. Convincing as was the evidence, the new principle, so potent in its now realized possibilities, was a laggard at first.
>
> "Now, just a paragraph concerning the onset and continuously developing science of bacteriology in its many obviously fruitful associations with our work: The main things we began to learn were that bacteria are associated with all active inflammatory lesions. That was Lister's great discovery, wasn't it? That they vary in important ways in kind and properties. That efficient postoperative drainage, usually *per vaginam*, for the most part takes care of any left behind it. Further, that we must be most careful while operating to prevent spreading localized infections beyond the field of operation. You may recall that Lawson Tait, right under Lister's nose, said that he would be willing to pack his wounds with dry germs."

Robert U. Massey, M.D.

IN MEMORIAM

BROOKS, PAUL L., McGill University, 1937. Dr. Brooks was a general practitioner in the Fairfield County area since 1938. He was on the staff of Bridgeport Hospital. Dr. Brooks was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died June 18, 1986 at the age of 89.

CHACE, CHARLES W., Yale University, 1952. Dr. Chace was a general practitioner in the Middlesex County area since 1955 during which time he served as an assistant state medical examiner. He was former medical staff president at Middlesex Memorial Hospital and medical director of both the Stonegate School in Durham and the Meadowbrook Convalescent Hospital in Middletown. He also served as Durham health director from 1966 to 1972. Dr. Chace was a member of the Middlesex County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 16, 1986 at the age of 63.

DAUTRICH, ALBERT, W., Yale University, 1939. Dr. Dautrich was a general practitioner in the Litchfield County area since 1946. He retired in 1981. Dr. Drautrich was a member of the Litchfield County Medical Association and the Connecticut State Medical Society; died May 3, 1986 at the age of 73.

DEMING, EDWARD G., Harvard Medical School, 1940. Dr. Deming was a plastic surgeon in the Hartford County area since 1947. He is chief of plastic surgery at Newington Children's Hospital and was the senior plastic surgeon at Hartford Hospital. Dr. Deming was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 28, 1986 at the age of 71.

DWYER, GREGORY K., University of Rochester Medical School, 1943. Dr. Dwyer was an otolaryngologist in the Fairfield County area since 1947. He served as chief of staff at Norwalk Hospital from 1968 to 1970 and he also introduced microscopic ear surgery to the Fairfield County area. Dr. Dwyer was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died May 19, 1986 at the age of 69.

GOLDEN, ARCHIE J., Yale University, 1950. Dr. Golden was a family practitioner in the Hartford County area since 1952. Before retiring in 1985, he was a member of the staff of Hartford Hospital and served as medical director of several nursing homes in the greater Hartford area. Dr. Golden was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died May 9, 1986 at the age of 66.

HISCOCK, IRA V., M.P.H., Yale University, 1921. Professor Hiscock was a leader in public health programs in the United States; was a member of the faculty at Yale University from 1920 to 1960, retiring as Anna M. Lauder Professor of Public Health and Chairman of the Department of Public Health. He received numerous honors, one of which was an honorary doctor of medicine degree from the Connecticut State Medical Society. Professor Hiscock was a former consultant at Yale-New Haven Hospital; died April 4, 1986 at the age of 93.

KLATSKIN, GERALD, Cornell Medical School, 1933. Dr. Klatskin was an internist in the New Haven County area since 1937. He was a pioneer in the development of liver biopsy techniques and their histological interpretation. Dr. Klatskin was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 27, 1986 at the age of 75.

LISKER, BERNHARD H., Yale University, 1975. Dr. Lisker was a cardiologist in the Fairfield County area since 1982. He was on the staff of Danbury Hospital. Dr. Lisker was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died April 8, 1986 at the age of 36.

NOVICK, JAMES L., St. George's University, 1984. Dr. Novick practiced physical medicine at the Hospital of St. Raphael since 1984. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Novick died April 15, 1986 at the age of 38.

WIES, CARL H., Yale University School of Medicine, 1932. Dr. Wies was an internist in the New London County area since 1932. He was on the staff of the Lawrence & Memorial Hospital. Dr. Wies was a member of the New London County Medical Association, the Connecticut State Medical Society and the American Medical Association; died April 22, 1986 at the age of 79.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

AMBULATORY CARE

Physician with primary care/ambulatory care/emergency medicine experience and background, for part-time position in Ambulatory Care Center. Send curriculum vitae to: Medical Director, Immediate Health Care, 4490 Main St., Bridgeport, CT 06606.

EMERGENCY MEDICINE

Full-time position for American trained physician in community hospital in NW Connecticut. Send CV to Lawrence Ward, M.D., Winsted Memorial Hospital, Winsted, CT 06098.

FAMILY PRACTICE

Family practitioner needed to join fast growing two physician practice in Danbury-Waterbury area. Please forward C.V. to, Director, Family Health Care Center, 141 North Main St., Southbury, CT 06488. (203) 264-8884.

Young, expanding group practice in Western Connecticut seeking BC/BE family practitioner to join family practice in existing office. Highly desirable area. No OB. CV to: Brookfield Health Associates, P.C., 940 Federal Road, Brookfield, CT 06804.

INTERNAL MEDICINE

Practice For Sale. Internal Medicine and Cardiology practice immediately available. High quality, well-established practice in New Haven, CT. Fully equipped, staffed office. Scheduled appointments awaiting energetic BC/BE physician. Opposite major hospital. (203) 624-5037.

CARDIOLOGIST. BC/BE. Needed in busy invasive and noninvasive cardiological practice. Please send CV to Stephen T. Sinatra, M.D., F.A.C.C., 483 West Middle Turnpike, Manchester, CT 06040. (203) 643-5101.

MISCELLANEOUS

Staff Physician. Masonic Charity Foundation is currently seeking a physician to join the staff at it's 650 resident multi-licensed JCAH approved Wallingford Campus which includes a 150 unit continuing care retirement community. Geriatric experience preferred but will consider internists and new graduates. Standard workweek with rotation of evening and weekend call. Excellent work environment, central Connecticut location, and full range of employee benefits. Salary will be commensurate with experience. Please send curriculum vitae with salary requirements to: Dr. Erlinda Rauch, Medical Director, Masonic Charity Foundation, P.O. Box 70, Wallingford, CT 06492. An Equal Opportunity Employer.

OBSTETRICS/GYNECOLOGY

Excellent opportunity for progressive BE/BC Obstetrician/Gynecologist to establish practice at the Family Childbirth Center. Arrangement to be negotiated to ease the cost of a start-up practice. For information call 787-2041 or send CV to Family Childbirth Center, 40 Temple St., New Haven, CT 06510.

FOR SALE. Ob/Gyn practice with office close to modern hospital. Northwest Connecticut, country living. University center easy travel. Retiring. Gross $300,000. Will introduce during transition. Write CSMS, c/o OB/CC.

Young solo OB/GYN, Board Certified seeks BE/BC Associate for busy private practice in a beautiful resort community in southern Connecticut. Excellent opportunities for higher education, water recreation, shopping. Easy access to New York City, Boston, Hartford, Cape Cod and skiing. Very stable economy with low unemployment. Please forward CV to: Stanley P. Solinsky, M.D., 449 Montauk Ave., New London, CT 06320 or call (203) 447-2377.

Central Connecticut. Full service community hospital wishes to attract solo practitioner, BC/BE, for private practice. Growing population base; central location. Excellent opportunity for affiliation with a progressive Medical and Administrative staff Incentive program available to qualified applicant. Send CV to CSMS, c/o OB/LL.

PART-TIME

Hospice Physician, part-time day position with some on call responsibilities available on the medical staff of the nation's first hospice. The Connecticut Hospice is a JCAH accredited hospital with a 44-bed inpatient facility and a hospice based home care program of 50 patients. Excellent opportunity for a physician interested in palliative care. Connecticut license required. Board certification preferred. Please send C.V. to John M. Stober, Director of Human Resources, The Connecticut Hospice, Inc., 61 Burban Drive, Branford, CT 06405. E.O.E.

PEDIATRICS

Medical Director—Pediatrician 12-20 hours. Residential school for multihandicapped children to age 21. Infirmary, nursing staff, consultants. Need pediatrician for direct medical care and overall supervision of health needs. Contact Anne Lasser, (203) 242-2274.

Seeking second Neonatologist for a 400+ bed, Central Connecticut General Hospital. University of Connecticut affiliate. Responsibilities to include clinical care in busy, Level II nursery and implementation of planned expansion to designated Level II unit in regional program. Interest in management of older, acutely ill children desirable. Ample opportunity for teaching and research interests. Direct inquiries to A. M. Capriglione, M.D., Chief of Pediatrics, New Britain General Hospital, 100 Grand St., New Britain, CT 06050.

PHYSICIANS WISHING TO PRACTICE IN THE STATE OF CONNECTICUT

EMERGENCY MEDICINE

Sept. '87. Age 41. Presently in practice. FLEX. AB elig. MD, Meharry Medical College, Nashville, TN. Int., Hubbard Hospital, Nashville; Res., Hubbard Hospital (General Surgery). Prefers institutional type practice in a large-sized community. Write, William T. Carter, Jr., M.D., 2252 MCDEC Quantico, VA. 22134.

FAMILY PRACTICE

July '87. Age 28. Nat'l bds. AB elig. MD, University of Pittsburg; Int. and Res., St. Margaret Memorial Hospital. Prefers group or associate type practice in a medium-sized community. Write, Peter M. Ripley, M.D., 919 River Oaks Dr., Pittsburgh, PA 15215.

March '86. Age 37. Licensed in Connecticut. MD, B.J. Medical College, Gujrat State, India; Int., B.J. Medical College affiliated hospitals; Res., Maelor General Hospital, Wales, United Kingdom (Gen. Surg.) and various hospitals approved by Royal College of Obstetricians and Gynecologists of England, (OB/GYN). Prefers family practice in group, solo, or institutional medicine. Write, Dr. V. Patel, M.D., 155 Bull Hill La., West Haven, CT 06516 or call (203) 934-8876.

GENERAL PRACTICE

Availability negotiable. Licensed in Connecticut. Age 34. Nat'l bds. AB cert. MD, UConn, Farmington; Int., Griffin Hospital, Derby; Res., Conn. Valley Hospital, Middletown. Also interested in psychosomatic medicine and rehabilitation medicine. Prefers group, associate, institutional or industrial type practice. Write, P.O. Box 239, Higganum, CT 06441.

Jan. '86. Age 47. Licensed in Connecticut. FLEX. AB elig. MD, Cairo University Medical School, Cairo, Egypt; Int. and Res., Rhode Island Medical Center and Iowa University Hospitals; Fellowship, Indiana University School of Medicine. Desires general medicine position in institutional or industrial type practice in a small to medium-sized community. Write, CSMS, c/o MG/ANES.

GENERAL SURGERY

Vascular. Aug. '87. Age 32. Nat'l bds. AB elig. MD, University of Medicine and Dentistry of New Jersey; Int., Res. and Fellowship, Northwestern University of Pennsylvania. Prefers group, associate or institutional type practice in a medium to large-sized community. Write, John W. Francfort, M.D., 215 E. Chicago Ave., Apt. 2312, Chicago, IL 61611.

INDUSTRIAL AND INSTITUTIONAL MEDICINE

Immediately available. Presently in practice. Age 63. Nat'l bds. AB elig. MD, NY Upstate Medical Center, Syracuse, NY; Int., USC/Los Angeles City Hospital, Los Angeles, CA; Res., University of San Francisco. Seeking a Directorship either with a company or multi-specialty group. Has been in Occupational Medicine for 19 years. Write, James W. Fitzgerald, M.D., 8800 Vine Valley Dr., Sun Valley, CA 91352.

INTERNAL MEDICINE

Feb. '87. Presently in practice. Age 39. Nat'l bds. AB cert. MD, Tufts Medical School, Boston, MA; Int. and Res., The Hospital of St. Raphael, New Haven. Prefers group or associate type practice. Write, Michael Collins, M.D. 8259 Toll House Rd., Annandale, VA 22003.

INTERNAL MEDICINE

Immediately. Age 40. Presently in practice. Nat'l bds. AB cert. MD, New York University; Int., Maimonides Medical Center, NY; Res., Beth Israel Medical Center, NY. Prefers permanent part-time or full-time without major coverage responsibilities. Would also cover office hrs/nursing home rounds for busy group. Write CSMS/ c/o SN/IM.

Oct. '86. Age. 31. FLEX. AB elig. MD, University of Witwatersrand, So. Africa, Int., Wanganui, New Zealand; Res., St. Ann's Hospital, London, Old Church Hospital, Rush Green Hospital, Barnet General Hospital, London, England. Prefers group type practice. Write, Stephen J. Stanton-Reid, M.D., 207 Greystone La., Apt. 19, Rochester, NY 14618.

Seeking BC/BE Internist to walk into retiring partner's practice. Office located across the street from Manchester Memorial Hospital, Manchester, CT. Guaranteed base salary with incentives. Call (203) 646-1167 or send to Daniel Tardif, M.D., 56 Haynes St., Manchester, CT 06040.

HEMOTOLOGY/ONCOLOGY. July '87. Age 34. Nat'l bds. AB Cert. MD, Albany Medical College, NY; Int., Naval Hospital, Bethesda, MD; Res., and Fellowship, Naval Hospital, San Diego, CA. Prefers solo, group or institutional type practice in a medium to large-sized community. Write John J. Nanfro, M.D., 9118 Kirkdale Rd., Bethesda, MD 20817.

ORTHOPEDIC SURGERY

July '87. Age 33. Nat'l bds. AB elig. MD, Loma Linda University, Loma Linda, CA; Int., LA County/USC Medical Center, Los Angeles; Res., Wilford Hall Medical Center, USAF, San Antonio, TX. Prefers group or associate type practice in a medium to large-sized community. Write, Wayne C. Amendt, M.D., 327 Harman Blvd., Dayton, OH 45419.

PATHOLOGY

Board certified Pathologist, AC-CP, available in Connecticut for Locum Tenens or part-time position. Please phone (203) 224-5584.

Sept. '86. Age 38. Licensed in Connecticut. Presently in practice. Nat'l bds. AB cert. MD, University of North Carolina; Int. and Res., Rhode Island Hospital, Providence, RI; Res., (Path) Yale New Haven Hospital. Prefers solo, group, associate or institutional type practice. Write, Richard N. Pierce, M.D., 14313 Piccadilly Rd., Silver Spring, MD 20906.

PEDIATRICS

Sept. '87. Presently in practice. Age 31. Nat'l bds. AB cert. MD, University of Oregon, Portland, OR; Int. and Res., Mt. Zion Hospital, San Francisco, CA. Prefers a group type practice. Write: CSMS, c/o GT/PED.

PEDIATRICS/INTERNAL MEDICINE

Oct. '86. Age 36. FLEX. AB elig. MD, Universidad Autonoma de Guadalajara, Mexico; Res., Mercy Hospital, Baltimore, M.D. (PED); VA Hospital, Long Beach, CA (IM). Prefers solo, small group or associate type practice in a small community. Write, Michael F. Schafle, M.D., 1754 E. 2nd Street, Long Beach, CA 90802.

UROLOGY

July '87. Age 30. Nat'l bds. MD, Bowman Gray; Int. and Res., Medical College of Virginia. Prefers a group type practice in a medium-sized community. Write Steven E. Marks, M.D., 9207 Groundhog Dr., Richmond, VA 23235.

July '87. Age 30. Nat'l bds. AB elig. MD, University of Texas Medical School, Houston; Int. and Res., University of Texas affiliated Hospitals. Prefers group type practice in a medium-sized community. Write CSMS, c/o RD/UROL.

Current Status of Liver Transplantation

ROBERT T. SCHWEIZER, M.D., STANLEY A. BARTUS, M.D. AND
HENRY B. C. LOW, M.D.

ABSTRACT—Liver transplantation is an amazingly complex procedure. Several technical and immunological developments in the past decade have greatly improved the results. Three major advances are the development of an extracorporeal shunt, a commitment to re-transplantation when needed, and the use of drug combinations for immunosuppression based upon the new and unique drug, cyclosporine. One year survival is approximately 75% for children and 60% for adults, and further improvement is expected.

Transplantation of the liver, the largest abdominal organ, is medicine's equivalent to placing a man on the moon. The technical, physiological, and immunological hurdles were so great that liver transplantation was virtually impossible a little more than two decades ago. Recent developments have resulted in a steady increase in successful liver transplantation. While the procedure cannot yet be considered a routine clinical procedure, the current results are such that many patients with end-stage liver disease now have a realistic chance for prolonged survival. This report will review the recent important advances resulting in this remarkable achievement.

Historical Development

Successful liver transplantation in animals was reported in the late 1950's and early 1960's.[1,2] The most outstanding work was that of Dr. Thomas Starzl who performed the first human liver transplant in 1963.[3] The clinical application of this surgical therapy, however, proved to be far greater than the laboratory experience suggested. Although experimental work in animals was essential to the development of the surgical techniques, many of the problems encountered in clinical liver transplantation are in large part due to the underlying liver disease. Another problem not encountered in the laboratory is the condition of the liver from the human cadaver donor. These additional clinical factors often contribute to serious problems during the operative procedure in man.

While relatively simple in concept, orthotopic liver transplantation is an enormously complex procedure. Some of the early serious problems encountered were intraoperative hemorrhage, physiologic derangements during the anhepatic phase (time during vessel anastomoses), the presence of a hemorrhagic bleeding diathesis due to liver dysfunction, hemorrhage and the need for blood replacement, the limitations of liver preservation, occasional air embolism, post-operative respiratory and renal failure, and difficulties with biliary tract reconstruction. Superimposed on all of these problems is the poor nutritional status of the patient with advanced liver disease. Successful liver transplantation is a tribute to the early pioneers in liver transplantation, Dr. Thomas Starzl working in Denver, and Dr. Roy Calne in Cambridge, England who led their teams in overcoming these formidable barriers.

The major advances in liver transplantation in the past decade are in two general areas. One is the surgical and technical aspects, such as transfusion methods for the prevention and management of the bleeding diathesis. The second is in the prevention and control of the allograft rejection process—the body's natural defense mechanism aimed at destruction of any foreign tissue or organ transplant.

Technical Advances

Many of the technical advances center around the operative procedure, especially the period when there is no functioning liver. The numerous physiologic changes occuring at that time are managed by specially trained anesthesiologists, who have also been responsible for many of the technical advances.

One of the most important recent developments in the control of intraoperative problems has been the establishment of an extracorporeal shunt.[4] While a shunt has been routinely used in laboratory animals, necessitated by the lack of collateral circulation due to the absence of portal hypertension in the experimental animal, the shunt

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was only recently used in human liver transplantation. The need for a shunt arises from the fact that a portion of the vena cava and portal vein are removed with the recipient's native liver at the time of the transplant. Therefore, all venous return to the heart via the inferior vena cava and portal vein must be temporarily stopped. Venous pooling and hypertension develops in the mesenteric veins, kidneys, etc. By shunting blood from the portal vein and inferior vena cava, with the aid of a pump, blood can be returned rapidly to the right side of the heart through an internal jugular vein or axillary vein.

Patients with considerable portal hypertension do not necessarily need the shunt, but the physiologic benefits are such that it is almost routinely used in adults. In addition, placement of the shunt early in the operation may provide decompression of the portal system, resulting in less capillary hypertension which diminishes hemorrhage while the recipient's liver is being removed.

Removal of the recipient's liver continues to be the major source of hemorrhage due to scarring and portal hypertension. Patients with previous porta-caval shunts are particularly difficult because of the need to take down the portal vein-vena caval anastomosis. Blood from intestines must enter the liver *via* the portal vein in order to have a well functioning liver transplant. The very thin walls of the collateral veins and surrounding scar can make this aspect of the surgery extraordinarily difficult. Rapid, large volume hemorrhage is occasionally encountered.

In order to replace blood adequately during a period of excessive blood loss, a rapid infusion device has been developed. This involves a reservoir in which blood continues to circulate at a warm temperature, and a pump permiting rapid infusion up to two liters per minute. This device also has obvious usefulness in other types of surgery, such as major trauma cases.

The use of a cell saver is also beneficial during the liver transplant procedure. Unfortunately, older machines were not able to keep up with the blood loss in many cases, placing a great demand on blood banks to provide blood for transfusion. A new type of cell saver permits a very rapid turn-around time, so that a unit of blood can be available for reinfusion within a few minutes of recovery. Another problem with cell savers in the past was the large amount of heparin that was needed, but this has now been reduced to a level where it is rarely, if ever, a clinical problem.

Many of the patients coming to surgery will have a bleeding diathesis due to inadequate synthesis of clotting factors as a consequence of their advanced liver disease. Therefore, replacement of clotting factors becomes an immediate necessity. This can be accomplished with fresh frozen plasma. The presence of hypersplenism can occasionally lead to thrombocytopenia and rapid hemorrhage will also delete clotting factors, including platelets. Therefore, there is a need for constant monitoring of the nature of the bleeding diathesis so that appropriate replacement can be undertaken. A special apparatus used to monitor changes in coagulaton is the thromboelastograph. This device will rapidly indicate the type of coagulation defect that may have developed and indicate appropriate therapy.

There has been little change in the vascular anastomotic procedure which is essentially re-establishment of normal anatomy (Figure 1). The use of polypropylene suture material, however, has permitted a better hemostatic suture line than was possible with older materials, but it can easily result in stricturing unless careful attention is paid to the amount of tension left on the suture line. A newly described "growth factor" technique, developed for liver transplantation vessel suturing, will prevent anastomotic stricturing.[5]

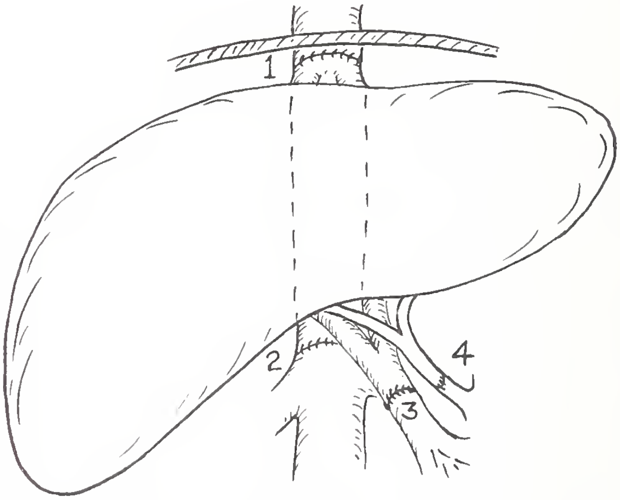

Figure 1
Anastomoses performed for orthotopic liver transplantation: 1, supra-hepatic inferior vena cava; 2, infra-hepatic inferior vena cava; 3, portal vein; 4, hepatic artery.

Reconstruction of the extrahepatic biliary drainage was at one time the Achilles' heel of liver transplantation. While other technical aspects were being overcome, survivors frequently developed bile duct stricturing, anastomotic leakage, or obstruction due to intraductal sludge. The gallbladder was once thought to be an ideal means of biliary drainage, since it could be anastomosed to the duodenum or a Roux-Y limb of jejunum. Unfortunately, that method had a 30% failure rate. This appeared to be due to a blockage in the cystic duct. An experimental study in our Surgical Research Laboratory showed that the blockage was probably due to periductal lymphatic engorgement.[6]

The ideal method of biliary reconstruction is an end-to-end anastomosis since it preserves the protective mechanism of the sphincter of Oddi. Because bile ducts in donor livers are often small, i.e., normal, this anastomosis can be difficult. A small degree of narrowing would result in a major stricture. In addition, some patients, such as those with biliary atresia or sclerosing cholangitis, do not have suitable recipient bile ducts and a Roux-Y limb of jejunum must be used.

A major improvement in this area has been the use of microvascular surgical techniques. This is the use of very fine suture material, magnification, microvascular instruments, and properly focused light provided by a headlamp. The avoidance of complications in biliary drainage has been a major advance in liver transplantion.

Another major advance has been improved methods of liver preservation. This was accomplished by using the same type of electrolyte solution that has been successfully used in kidney transplantation. This method permits preservation up to eight hours, with the principal means of preservation being hypothermia. Further lengthening of the preservation time would undoubtedly ease the logistical problems of always having to perform the liver transplant as an emergency procedure.

Since the preservation time is currently limited to eight hours, procurement of distant livers can be safely done only with the use of jet aircraft. While this at first appears to be a tremendous expense, it does not appear to be extraordinary nor inappropriate when compared to some other relatively expensive items used in medicine. For example, most of the chartered flights are less expensive than some frequently used prosthetic devices, such as total hips or pacemakers.

Immunologic Advances

Liver transplantation has benefited from the major discoveries that have occured in renal transplantation. For example, the measures used to prevent and reverse the rejection process in renal transplant recipients are directly applicable to liver transplant patients. Since larger numbers of kidney transplants are performed annually, there is a wealth of knowledge to be transferred from kidney transplantation to liver transplantation.

The most important development for the control of the rejection process in the past few years has been the discovery and clinical application of cyclosporine. This compound is unique in that it has a major effect upon cells involved with the early stage of the response to the implantation of a foreign tissue. While cyclosporine is a powerful immunosuppressive drug, it is nephotoxic in higher doses, and it will not prevent all rejection episodes. When used in combination with other common immunosuppressants, such as corticosteroids, antithymocyte globulin, azathioprine (Imuran^{R}), or the newer monoclonal and anti-T cell antibodies, synergistic effects can be obtained. Thus, lower doses of cyclosporine can be used, resulting in fewer side effects.

An important procedure in liver transplantation is monitoring of cyclosporine drug levels. Very high levels are associated with nephrotoxicity and also the emergence of serious infections, such as those caused by fungus or virus. An occasional lymphoma has developed in patients receiving large doses of cyclosporine. Measurement of cyclosporine blood levels with a radioimmunoassay, a very convenient method in most kidney transplantations, can be unreliable in the liver transplant patient during periods of liver dysfunction. This is primarily due to the accumulation of breakdown products of cyclosporine which are not immunologically active, but are measured by the radioimmunoassay. Therefore, a liquid chromatography assay must be used in the liver transplant with abnormal liver function.

An additional problem with the use of cyclosporine is that it can be rapidly eliminated in some patients, especially children. Therefore, immunosuppressive levels of cyclosporine may not be present in the very early post-transplant period, a time when acute rejection episodes are most frequent and most severe. This has been one of the major reasons for early irreversible failure of a liver transplant necessitating re-transplantation.

The role of tissue typing in liver transplantation is a relatively minor one. While a close histocompatible match can certainly be viewed as beneficial, as evidenced by the vast experience in renal transplantation,[7] the paucity of suitable cadaver donors currently offered for liver transplantation necessitates the use of almost any liver that is physiologically and anatomically suitable for transplantation.

A recent advance in the management of the liver transplant patient is the use of frequent liver biopsies in order to diagnose rejection activity, and response to immunosuppression.[8] Our initial experience with liver transplantation strongly confirms this view. We believe that the simple monitoring of biochemical liver function tests has a very poor correlation with the rejection process. For example, in addition to the allograft rejection process, liver dysfunction is occasionally due to a medication (which includes cyclosporine), viral hepatitis, preservation injury, or bile duct obstruction. An example of how liver biopsies are useful in guiding therapy is shown in Figure 2.

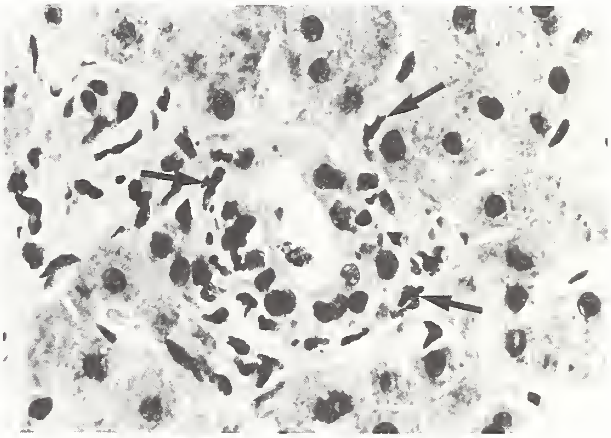

Figure 2

Needle biopsy of liver transplant in a 25 year old male during a period of alkaline phosphatase and transaminase enzyme elevation. These enzyme changes could have been interpreted as evidence of a rejection episode. The bile duct in this photomicrograph shows a polymorphonuclear infiltrate (arrows) which cleared after administration of antibiotics. The patient had no fever or other symptoms of cholangitis. H & E stain; 400X.

Percutaneous needle biopsy of the transplanted liver can be performed easily and safely through an anterior approach, a technique that was developed for liver transplantation by James Williams, M.D.[8] We have now performed approximately 50 liver biopsies in nine liver transplant patients with no complications.

Results of liver transplantation have also improved because of an awareness of referring physicians that the nutritional status of the patient often directly correlates with a successful outcome. Referring patients before they enter into a rapidly progressive terminal phase is of obvious importance. The poor nutrition due to the anorexia that accompanies advanced liver disease can often be overcome with the use of a simple feeding tube and appropriate nourishment by that means, especially in children.

Indications for Liver Transplantation

The usual candidate for liver transplantation is a person of a relatively young age (under 55 years) with irreversible chronic progressive liver disease. The liver disease should have progressed to the stage that survival beyond six months is very unlikely. Contraindications for orthotopic liver transplantation are portal vein thrombosis, severe hypoxemia, sepsis, severe non-hepatic disease which would limit survival, such as cardiac or pulmonary disease, and noncompliance of the patient.

The alcoholic with cirrhosis is not a candidate for liver transplantation unless a documented period of sobriety can be clearly established. A minimum of six months is considered necessary by some centers but other centers, including ours, prefer at least one year of abstinance prior to consideration for liver transplantation.

Diseases most suitable for liver transplantation are primary biliary cirrhosis, postviral hepatitic cirrhosis, and congenital abnormalities such as biliary atresia. A few patients with primary hepatic cancer may be candidates, depending upon the type of tumor and absence of metastatic disease.[9]

Liver Donors

Donors for hepatic transplantation are patients suffering total and irreversible loss of brain function, but who continue to have adequate circulation because of ventilatory and circulatory support. They are the same patients that are used for kidney and heart donation. For liver donation, arterial hypoxemia should be avoided and relatively normal liver function tests are necessary. In addition, there should be no history of chronic severe alcohol intake. Kidneys are also usually removed for transplantation, and in most cases the heart and even pancreas can be recovered for transplantation.

Unfortunately, families do not as frequently agree to liver donation as they do to kidney donation, resulting in fewer liver donors. It is therefore unlikely that a transplant center would have a suitable liver donor at its own hospital and in the time required for a seriously ill potential liver transplant recipient. This necessitates travel by the transplant team to a liver donor's location. The time for travel requires some form of preservation of the liver prior to transplantation. It is also unfortunate that livers are not as easily preserved as are kidneys. However, as previously mentioned, adequate preservation of the liver can currently be obtained up to approximately eight hours. With the use of jet aircraft transportation, livers can be procured from distances up to 1,500 miles.

Results

The results of liver transplantation are improving so rapidly that it is very likely that the statistics presented in this report are already outdated. Currently, children receiving an orthotopic liver transplant have approximately a 75% chance of surviving one year.[10] This figure, however, includes those requiring re-transplantation.

Re-transplantation is an extremely important concept, since it must be realized that when irreversible liver rejection has occurred, the only chance for survival is to perform another liver transplant. This concept has been fundamental to improving the overall results of liver transplantation in the past five years.

While the results of liver transplantation in adults are not as good as in children, approximately 60% of the patients will be alive one year after the transplant.[10] Further improvement can be expected with better methods of immunosuppression currently under evaluation, and simply by earlier referral of patients.

Chronic rejection can be a late complication in the liver transplant patient as it is in heart and kidney transplantation. When advanced, re-transplantation becomes the only course of therapy. However, timing is very important, as not all patients with chronic rejection will require immediate liver re-transplantation. With better methods of immunosuppression, fewer patients will develop chronic rejection.

Costs

One of the current deterrants to more extensive application of liver transplantation is the cost. Hospital expenses alone are not always very great, especially if the patient has no serious complications. With prolonged hospitalization, due to either recurrent immunologic problems or to serious technical complications, costs could reach $250,000. The average cost for a liver transplant at the University of Pittsburgh was $80,000.[11]

When considering the *total* cost of care for these patients, however, one must also consider the care of patients with terminal liver disease who do not receive liver transplantation. The prolonged hospitalization of such individuals in the final months of their lives can result in a tremendous expense. It is very likely that successful liver transplantation will eventually become a much less costly therapy. Most liver transplant recipients have had their care paid for by private insurance companies. Many states, including Connecticut, will pay for liver transplantation in welfare patients.

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Pitfalls in the Diagnosis and Management of Blunt Splenic Trauma

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Introduction

Recent advances in the understanding of splenic immunologic function have precipitated a reassessment of mandatory splenectomy as a matter of course for blunt trauma to the spleen.[5,10,13,14,16,17] Reports of conservative (non-operative) treatment as well as splenorrhaphy have attained prominence in the literature as well as increasing clinical acceptance.[2,3,4,8,15,18,20] Critical to exercising these alternatives to splenectomy has been the importance of establishing adequate guidelines for operative intervention of any kind.[22] This study was undertaken at Yale-New Haven Hospital (YNHH) and Bridgeport Hospital (BH) to determine the relative significance (both alone and in combination) of physical exam, liver-spleen scan, and peritoneal lavage in the assessment of blunt splenic trauma.

Materials and Methods

The charts of adult patients admitted to YNHH during 1972-1981 (90 patients) and at Bridgeport Hospital since 1980 (15 patients), with the diagnosis of documented or suspected blunt trauma to the spleen, were retrospectively reviewed. Data obtained included demographic data, the presence or absence of hypotension on admission, physical findings and associated injuries as well as timing and form of surgical management (if any). Short term outcome and complications were evaluated. Results of liver-spleen scans, angiography, and peritoneal lavage were noted. Indications for surgery included worsening of peritoneal signs on physical exam, hemodynamic instability, positive lavage, or clinical and laboratory evidence of continued intra-abdominal bleeding. Splenic injury was documented at exploratory celiotomy (86 patients) or by persistent defects on computed tomography or spleen scans (19 patients).

Data were analyzed for significance with the chi-square test. A multiple linear regression was performed for the ability of various pre-operative data to predict splenic injury documented at operation. Data were analyzed using the SPSS program at the Yale Computer Center.

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Results

Mechanisms of injury for 105 patients were automobile and motorcycle accidents, vehicle-pedestrian accidents, assaults with blunt objects, falls, and industrial mishaps. There were 78 males (74%) and 27 females (26%). The frequency of physical findings is listed in Table 1. Left upper quadrant tenderness was the most common finding followed by the presence of peritoneal signs (51 percent of patients).

Table 1
PHYSICAL FINDINGS IN PATIENTS WITH SUSPECTED SPLENIC INJURY

	N	%
Left upper quadrant tenderness	87	83
Peritoneal signs	54	51
Transient hypotension	33	31
Persistent hypotension	7	7
Normotensive	65	62

As shown in Table 2, left rib fractures were present in 38 percent of patients, and a positive lavage (gross blood or >100,000 red cells) was found in 92 percent of the patients undergoing lavage (N=51). The accuracy rate for the liver-spleen scan was 78 percent with 50 patients undergoing this study.

Table 2
DIAGNOSTIC FINDINGS IN PATIENTS WITH SUSPECTED SPLENIC INJURY

	Total N	*Number (Percent)*
Left rib fracture	105	40 (38)
Positive peritoneal lavage	51*	47 (92)
Liver-spleen scan	50*	
True positive		32 (64)
True negative		7 (14)
False positive		2 (4)
False negative		9 (18)

* Not all patients underwent these studies.

Analysis using the chi-square and Pearson's test was undertaken to determine the ability of each of these diagnostic measures, alone and in combination, to predict the presence of splenic injury. The presence of peritoneal signs at the initial exam was highly suggestive of splenic injury ($p<0.0005$) as was a positive lavage ($p<0.003$). Other findings such as left rib fracture, left upper quadrant tenderness, hypotension upon presentation, number of systems injured, or liver-spleen scan did not correlate with presence or absence of splenic injury (Table 3).

Table 3
ABILITY OF PHYSICAL FINDINGS AND DIAGNOSTIC TESTS TO PREDICT SPLENIC INJURY

Study/Finding	*Significance Level*
Peritoneal lavage (positive)	0.0005
Peritoneal signs at initial exam	0.003
Peritoneal signs and positive peritoneal lavage	0.001
Left rib fracture and positive peritoneal lavage	0.01
Left rib fracture	N.S.
Left upper quadrant tenderness	N.S.
Hypotension in Emergency Room	N.S.
Number of other systems injured	N.S.
Liver-spleen scan	N.S.

Though no prospective protocol was utilized in the 105 patients in this series, a total of 45 patients were initially observed, 26 of whom ultimately came to operation. Of the 19 patients who were observed and then discharged 12 were felt to have definite splenic injuries documented either by serial positive liver-spleen scans correlated with falling hematocrit, with positive angiogram, or with CT scans. These 12 patients had no associated injuries and were never hemodynamically unstable. Fifteen of the 26 patients who came to surgery after a delay (range of 24 hours to 3 weeks) had clear splenic injuries by radiographic criteria, when it was elected to observe them. Of the 26 patients undergoing delayed operation, 16 had periods of hemodynamic instability (systolic BP <80 mmHg) that prompted exploration.

Delay in surgery due to observation of initially stable and/or initially undiagnosed patients who were awaiting serial exams, hematocrits and/or radiologic studies did not affect the incidence of complications. Complications included atelectasis or pneumonia (16%) and pancreatitis (4%), but miscellaneous single complications occurred in 11 patients (10%). Six patients died following splenic injury. All had periods of hypotension and of the four patients for whom complete data were available, all presented with hypotension which was refractory to volume and blood resuscitation. In addition four of the patients who died had greater than four organ systems injured. In the 86 patients who came to surgery, there were 59 associated organ system injuries as demonstrated in Table 4.

Table 4
ASSOCIATED SYSTEMS INVOLVED IN PATIENTS WITH BLUNT SPLENIC INJURY

# Patients	*Organ System*
11	Gastrointestinal
10	Genitourinary
10	Central Nervous System
17	Musculoskeletal
1	Cardiopulmonary

Discussion

The 105 patients reviewed in this study demonstrate age and sex distributions consistent with other reports and a complication rate similar to that reported in the literature.[1,9,18] The diagnostic accuracy of peritoneal lavage is within the range reported by other groups.[6]

Previous studies have reported the frequencies and implications of physical findings in patients with splenic trauma.[1,9] We have attempted to delineate the relative importance of each in predicting operative need and outcome. Of note in this study is the presence of left upper quadrant tenderness in all patients in contrast to the marked significance of peritoneal signs in those patients who ultimately required splenectomy. although the incidence of peritoneal signs noted in this retrospective study is probably higher than would be found in a prospective study, the presence of peritoneal irritation on initial exam should alert the examiner to the need for vigorous investigation utilizing the other criteria for operative intervention.

The question regarding the best diagnostic modality is addressed by the data on peritoneal lavage and liver-spleen scan. While the reliability of liver-spleen scan is believed to be high by some,[11] the inaccuracy of liver-spleen scan in this study makes it an unreliable diagnostic tool. In contrast, peritoneal lavage is well established as a diagnostic measure for associated intra-abdominal injury[6,12] which is present in blunt splenic trauma up to 40 percent of the time.[9,18] Radiologic studies would appear to be most useful in those situations in which peritoneal lavage is contra-indicated especially in view of the excellent accuracy now reported with abdominal CT scan[19] and the latter's ability to diagnose a multitude of intra-abdominal and retroperitoneal problems. CT scan appears to have a valuable role in selected patients.

Conclusion

Data presented in this study lead to several conclusions. First, positive peritoneal signs and/or positive peritoneal lavage are the best indicators of splenic injury. Second, left rib fractures, left upper quadrant tenderness, or transient hypotension alone are unreliable predictors of splenic injury. Third, liver-spleen scan is neither a very accurate test nor a reliable predictor of splenic injury. Finally, if peritoneal lavage is positive, it is recommended that patients with suspected splenic injury undergo exploratory celiotomy and control of hemorrhage (splenorrhaphy or splenectomy). This approach will allow rational triage of patients with blunt abdominal trauma and will prevent the dire consequences of a hypotensive crisis occasionally seen with "conservative" non-operative management.

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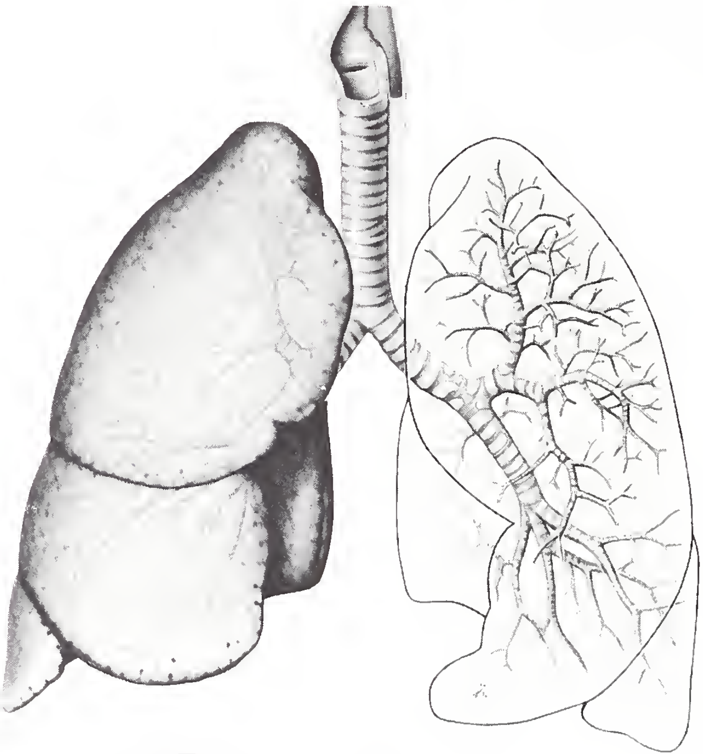
Consider the causative organisms...



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Brief Summary Consult the package literature for prescribing information

Indications and Usage Ceclor* (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae* and *S pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor

Contraindication Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics

Warnings IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS TO BOTH DRUG CLASSES

Antibiotics, including Ceclor should be administered cautiously to any patient who has demonstrated some form of allergy particularly to drugs

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins), therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics Such colitis may range in severity from mild to life-threatening

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C difficile* Other causes of colitis should be ruled out

Precautions *General Precautions* — If an allergic reaction to Ceclor* (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e g , pressor amines, antihistamines, or corticosteroids

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms Careful observation of the patient is essential If superinfection occurs during therapy, appropriate measures should be taken

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug

Ceclor should be administered with caution in the presence of markedly impaired renal function Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur This has been observed with Benedict's and Fehling's solutions and also with Clinitest* tablets but not with Tes-Tape* (Glucose Enzymatic Test Strip, USP, Lilly)

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis

Usage in Pregnancy — Pregnancy Category B — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor* (cefaclor, Lilly) There are, however, no adequate and well-controlled studies in pregnant women Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses Average levels were 0 18, 0 20, 0 21, and 0 16 mcg/ml at two, three, four, and five hours respectively Trace amounts were detected at one hour The effect on nursing infants is not known Caution should be exercised when Ceclor is administered to a nursing woman

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below

Gastrointestinal symptoms occur in about 2 5 percent of patients and include diarrhea (1 in 70)

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment Nausea and vomiting have been reported rarely

Hypersensitivity reactions have been reported in about 1 5 percent of patients and include morbilliform eruptions (1 in 100) Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor Such reactions have been reported more frequently in children than in adults Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy No serious sequelae have been reported Antihistamines and corticosteroids appear to enhance resolution of the syndrome

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients)

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40)

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40)

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200)

[061782R]

Note Ceclor* (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information

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Multiple Primary Neoplasms of the Female Genital Tract

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ABSTRACT—Multiple primary neoplasms of the upper female genital tract represent an uncommon, but well recognized entity. A case is reported in which histologic abnormalities of malignant and dysplastic type were seen in multiple organs in the genital tract from cervix to ovaries. The implications of the case are discussed with regard to the multicentric concept of tumorigenesis and the embryologic similarity of tissues in different areas of the genital tract.

Multiple primary neoplasms of the female genital tract represent an uncommon but well recognized entity. The incidence of multiple primary neoplasms of the upper female genital tract is reported to be less than 1%.[1] Some cases have demonstrated lesions with similar histopathologic findings, while others have had dissimilar lesions.[1-4] When multiple malignancies show similar findings, difficulty exists in determining whether this is truly a result of multiple primary neoplasia or rather metastatic spread from a single lesion.

We report a case in which histologic abnormalities of malignant and dysplastic type were seen in multiple organs in the genital tract from cervix to ovaries. Review of the literature failed to reveal a similar occurrence. The implications of this case are discussed with regard to the multicentric concept of tumorigenesis and the embryologic similarity of tissues in different areas of the genital tract.

Case History

A 42-year-old female, gravida 2, para 2, first presented to her private physician in October, 1981 with the complaint of vaginal discharge. Her gynecologic history was essentially unremarkable except for two normal vaginal deliveries in 1963 and 1968. She denied the use of any hormonal medications. She experienced phlebitis after her delivery in 1963 and developed osteoarthritis in 1970. The patient had not used talc powder, diaphragms, or lubricants. Both she and her husband worked as schoolteachers, and she denied any exposure to toxic chemicals.

Her physical examination was within normal limits. On pelvic exam, the cervix was without visible lesions and the uterus and adnexae were not remarkable. A cervical smear obtained at that time revealed mild atypia and she was treated with topical antibiotic cream. A cervical smear the following month indicated cellular changes strongly suggestive of malignancy.

The patient underwent dilatation and currettage of the uterus and cervical biopsy in December, 1981 which showed early secretory endometrium and adenocarcinoma in situ of the endocervix. She underwent a total abdominal hysterectomy and left salpingo-oophorectomy in February, 1982. The right ovary appeared normal at the time of operation. In July, 1982, the patient was referred to the Gynecology Oncology Clinic at the University of Connecticut Health Center where she was found to have an 8 centimeter cystic mass in the cul-de-sac. A right salpingo-oophorectomy was subsequently performed.

Pathology

The right ovary measured 8 x 6 x 5 centimeters and revealed a multiloculated cyst. The inner surfaces of the cyst were smooth and glistening. The cyst wall measured 0.4 centimeters in greatest thickness. The cystic spaces were filled with yellow serous fluid. The left ovary was also a multicystic structure measuring 9 centimeters in greatest dimension. The cyst chambers ranged from a few millimeters to 5.5 centimeters in diameter and contained thick mucoid fluid. Both tubes appeared normal. The body of the uterus showed a few fibrous adhesions on the serosal surface, but was otherwise unremarkable. The endometrium was thin and hemorrhagic. The endocervical canal contained a 1 centimeter smooth-surfaced polyp.

Microscopic examination of the cervix revealed extensive cytologic alterations in the columnar epithelium. This was seen both in the polypoid lesion and elsewhere in the endocervical tissue (Figure 1). The changes consisted of nuclear hyperchromasia, loss of polarity, cellular stratification and prominent mitotic activity. Mucin production was evident in a small proportion of the abnormal glands. The predominant pattern was intraepithelial, but in several areas, there was early invasion (Figure 2).

Sections of endometrium showed a proliferative pattern. Minimal but distinct cytologic atypia was present in scattered foci (Figure 3). This consisted of nuclear irregularity

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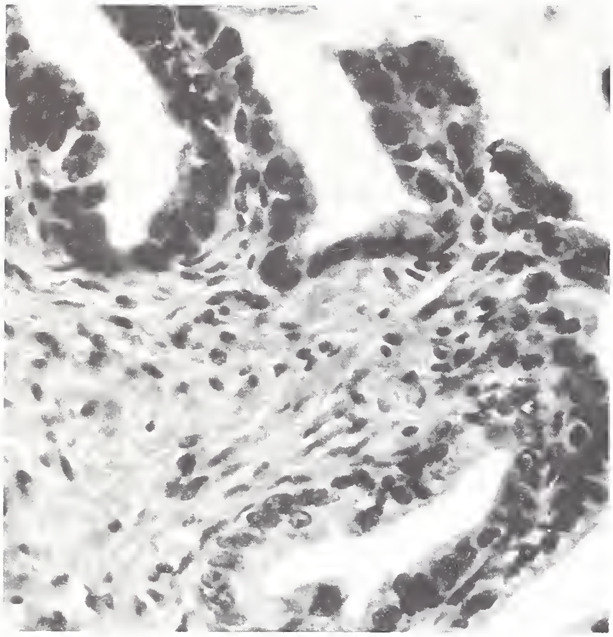

Figure 1

Section of cervical polyp showing changes consistent with carcinoma in situ. (H & E, X 150.)

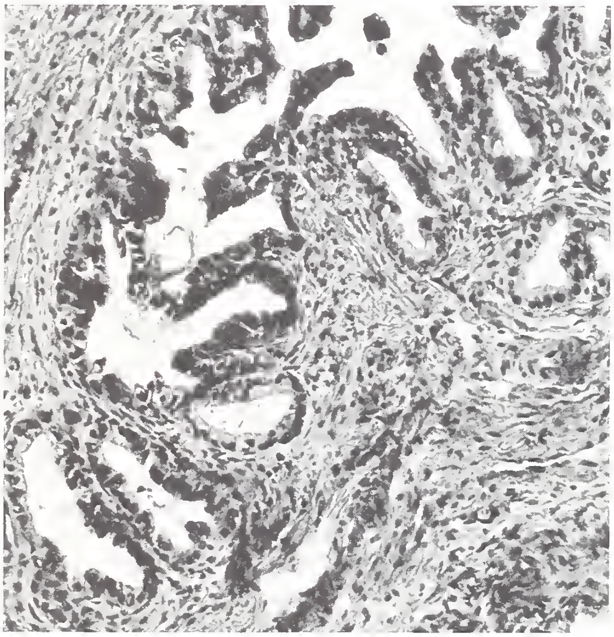

Figure 2

Adenocarcinoma of cervix with area of invasion. (H & E, X 175.)

with prominent nucleoli and altered polarity. The endometrium was otherwise unremarkable.

The tubes also demonstrated focal atypia in a widely scattered manner. Cells lining the mucosal fronds in these areas were enlarged and irregularity arranged. The changes were limited to the lining epithelium.

Both ovaries showed similar histologic findings. Cystic structures included a flattened lining generally occurring as a single layer. Some areas showed prominent mucin

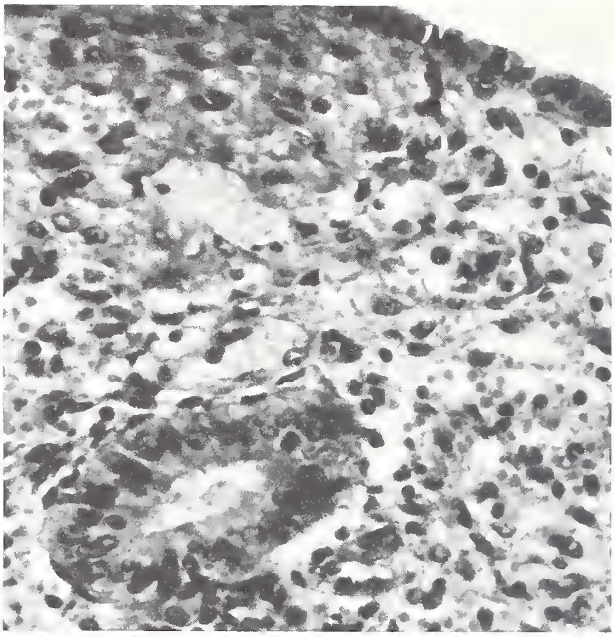

Figure 3

Endometrium shows focal nuclear atypia in surface epithelium and gland lining. (H & E, X 200.)

secretion. In both the mucinous and other areas, cystologic atypia was marked. Strips of epithelium could be seen with bizarre, hyperchromatic, highly irregular nuclei (Figure 4). Cytoplasmic appearance varied from clear to eosinophilic. No significant stratification or stromal invasion was seen.

The microscopic findings were interpreted as follows: adenocarcinoma of the cervix, mucin-secreting, with

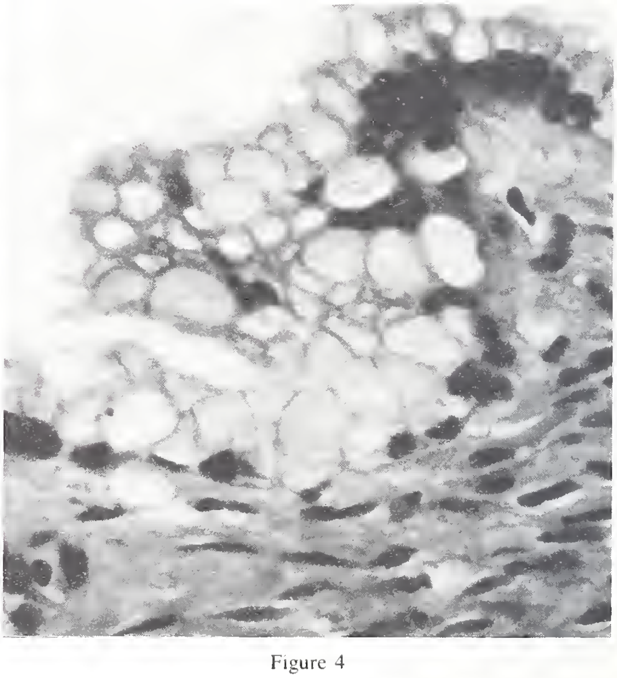

Figure 4

Mucinous area of ovarian cyst demonstrates prominent nuclear irregularity. (H & E, X 375.)

superficial invasion; adenocarcinoma in situ (mucinous cystadenocarcinoma in situ), left and right ovaries; columnar cell atypia, multifocal, mild endometrium and left and right tubes.

Discussion

Recent attention has been directed to the existence of multiple primary neoplasms of the upper female genital tract. In an extensive study by Diligdisch and Szulman, there was a 5.4% incidence of multiple primary carcinoma of the female genital organs and breast in their cancer population. The incidence of multiple primary lesions of the upper genital tract was less than 1%. Reports varied from those cases in which the multiple primary sites revealed different histologic types of tumor to those in which the microscopic patterns were identical.[1-4] When multiple areas of similar histologic appearance occur, controversy may exist as to whether this represents metastatic spread of true simultaneous multiple primary lesions.

Woodruff and Julian described 118 secondary carcinomas of the fallopian tube.[2] On statistical grounds from the 5-year survival data, it was implied that some of these cases may have represented multiple primary neoplasms since the survival seemed much better than that would be expected with metastatic disease. They suggested that regional influence of a carcinogen on embryologically similar tissues might be responsible for the findings.

A recent report by Cramer, et al examined the role of genital exposure to talc as a possible carcinogen and found that patients who used talc as a dusting powder in the perineum had a slightly increased relative risk of ovarian cancer as compared to women who did not.[5] A review of our patient's history indicated that she was not exposed to talc or any other known carcinogen.

The embryological similarity of tissues in different areas of the female genital tract may be an important factor in multiple primary neoplasia. The surface epithelium of the ovary and the Mullerian duct both develop from the coelomic epithelium of the posterior wall of the abdominal cavity. The paramesonephric or Mullerian ducts eventually develop into the fallopian tubes, uterus, and cervix. Since the structures of the upper genital tract have a common origin, they may respond in a similar manner to a regional carcinogenic agent.

In the present case, it is clear that the findings represent multiple primary lesions. The early nature of the abnormalities virtually excludes the possibility of metastasis from a single primary lesions. The in situ pattern in the ovaries and predominantly in situ changes with superficial invasion in the cervix suggest multiple fields of synchronous tumorigenesis in response to a regional neoplastic agent acting upon tissue of common embryological origin. The early nature of the various lesions seen supports such a field effect, but this interpretation remains to be substantiated by studies on additional cases.

Since tissues of similar origin may share a similar neoplastic response, the potential exists for delayed (metachronous rather than synchronous) responses in different sites. This indicates the need for diligent follow-up to detect the possible development of a second primary in embryologically similar areas. This may be especially important in the long-term follow-up of patients with borderline lesions of the ovary when conservative surgery has been performed and the uterus and tubes not removed.

In summary, this case represents the first reported instance in which atypical changes were seen throughout the Mullerian duct system and the associated ovarian surface epithelium. The findings support the significance of the concept of multiple primary neoplasms arising in embryologically similar tissue.

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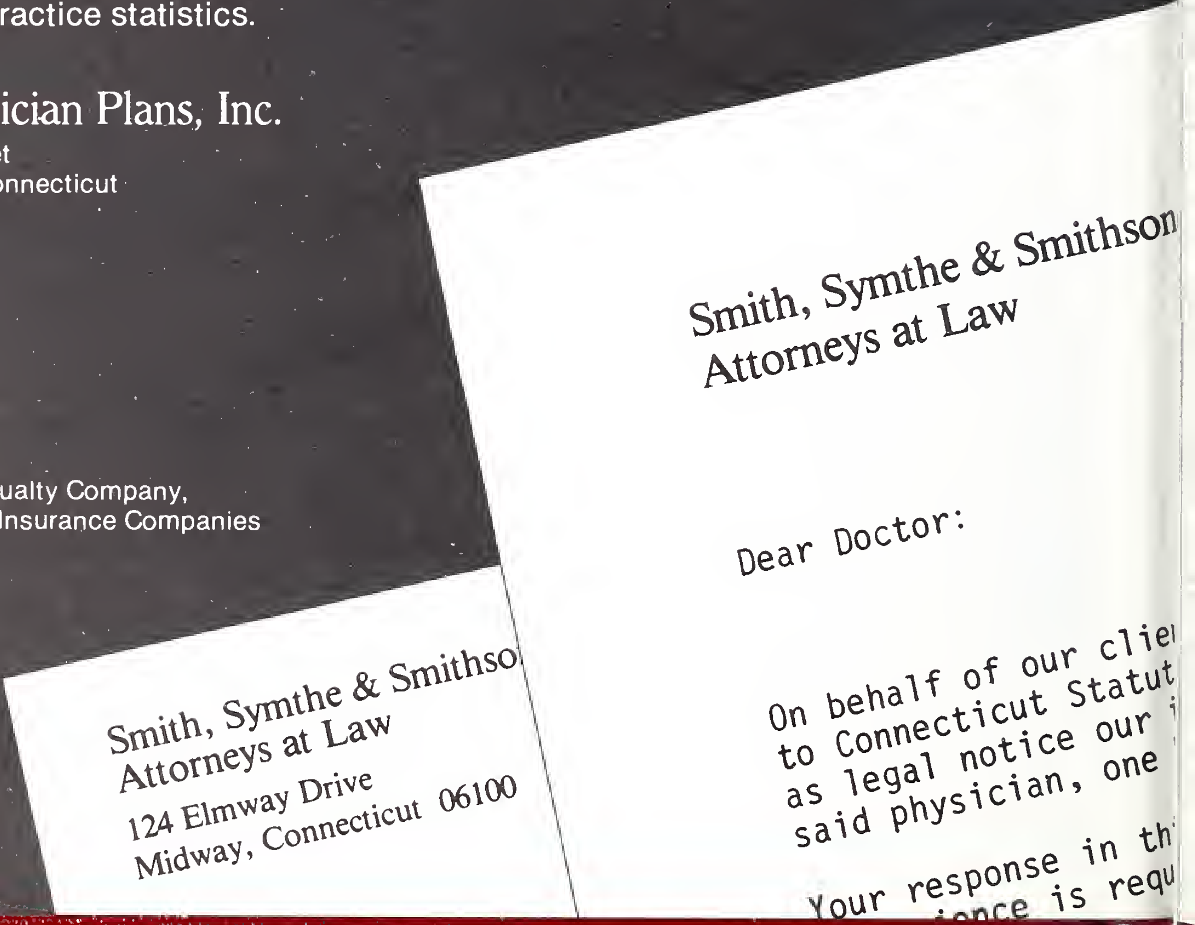

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Noninvasive Carotid Artery Evaluation by Duplex Doppler

JAN MALAT, M.D., KENNETH J.W. TAYLOR, M.D., PH.D. AND STEVEN MORSE, M.D.

Cerebrovascular disease is the third most common cause of death in the United States. In 1978, mortality from stroke exceeded 648,000 hospital admissions and 175,000 deaths.[1] Despite the high survival rate after the initial cerebral infarction, only 50% of patients recover from their neurological deficit and approximately 16% of stroke victims remain totally disabled. The prevalence of cerebrovascular disease increases with age being three times more common in those over 65 yrs. compared with those 45-65 yrs. of age. Of all the risk factors for this disease, age appears to be the most important.

Stroke results from ischemic injury to the motor or sensory tracts, usually in the region of the internal capsule, due to cerebral hemorrhage or vascular occlusion. Most cerebral infarcts are due to vascular occlusion which may occur indirectly by embolization from a distant source or directly due to thrombosis of a severely stenosed carotid or intracranial cerebral artery. Of these, the carotid bifurcation is the most prone to atherosclerotic disease with embolization or occlusion accounting for approximately half of such cerebral ischemic events.

The diagnostic approach to the diseased cerebrovascular system varies from institution to institution. At the Yale-New Haven Hospital, we intially use a completely noninvasive screening technique—duplex sonography.

The term "duplex" implies the simultaneous use of two diagnostic methods—ultrasound imaging and Doppler flow evaluation.(Figure 1) Conventional real-time ultrasound with high resolution transducers (7.5% – 10MHz) is helpful for spatial orientation and direct visualization of plaques and actual stenosis. The simultaneous use of Doppler discloses the flow characteristics in the vessel.

The Doppler effect is the change in a perceived frequency when sound is emitted from a moving source. A common example of the Doppler shift is the increase in frequency of a siren coming towards the observer and the decrease in pitch going away. Thus, the Doppler shift allows not only the detection of movement, but also the direction of movement and the velocity, since the change in frequency varies linearly with the velocity of the reflector. The difference between the emitted and returned frequencies is the Doppler shift which usually falls within the frequency range detectable by the human ear and, after amplification, this Doppler shift is the audio signal.

In the past, continuous wave Doppler was used to record the flow characteristics. This was used blindly without the use of simultaneous imaging. Good results have been obtained by a few very experienced operators, but false positives and negatives occurred, especially in less experienced hands. The combination of the two techniques, real-time ultrasound and Doppler, increases the sensitivity and accuracy for evaluation of carotid and occlusive lesions compared with results obtained by a single method. Imaging allows detection of atheromatous plaque and large ulcers while Doppler permits quantitation of the hemodynamic disturbance and hence the severity of the stenosis. Duplex scanning is limited by its inability to detect lesions above the mandible, below the clavicle and in the evaluation of the vertebro-basilar system. Therefore, angiography retains its importance as the definitive preoperative evaluation.

Digital intravenous angiography has been advocated as a less invasive method for opacifying and imaging the carotid vessels.[2] However, further experience has shown that there are many limitations in this technology, especially in the elderly.[3,4] Thus, at this institution, intra-arterial digital angiography using small catheters is used in 90% of patients in preference to the intravenous technique which involves a large dose of contrast medium injected into the central veins. In many patients, this procedure can be performed on an outpatient basis.

It appears that duplex techniques have similar accuracy to angiography in the evaluation of the proximal common carotid arteries and the bifurcation. Indeed in some reports, ultrasound was more sensitive than angiography in the detection of early stenosis.[5] Some surgeons now advocate surgery on the basis of the duplex scan alone

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in selected patients. However, as a general rule we advocate a preoperative angiogram to search for more proximal or distal disease than in the bifurcation alone and to evaluate the vertebro-basilar system, especially prior to vertebral or subclavian bypass. In addition, in view of the serious prognosis of a classic transient ischemic attack (TIA), there is a good argument for intra-arterial angiography in all such patients. In practice, many of these patients are not deemed to be acceptable operative risks and will be given antiplatelet therapy unless the stenosis is critical so that noninvasive examination is still preferred in many of these patients.

Indication for duplex scans:

The main objectives for ultrasound studies of carotid arteries are:

1. to visualize and evaluate plaques in carotid arteries.[6,7]
2. to quantify the carotid artery stenosis.
3. to detect the presence of collateral flow.

Referring clinicians are offered a simple noninvasive method without any ionizing radiation for highly accurate (about 95%) evaluation of common clinical complaints possibly related to the carotid arteries.[6,7]

Clinical indications for duplex sonography include:

1. Carotid bruit

Carotid bruit is present in approximately 4% of the elderly population, especially in females and hypertensives.[8] It is a non-specific indicator of widespread vascular disease and predicts a high probability of a cardio-vascular death. Although only present in 44 percent of people with significant carotid artery stenosis, it indicates the need for a full vascular evaluation including duplex Doppler examination of the carotid arteries. There is no justification for angiography as an initial procedure in these patients.

2. Atypical TIA

Intra-arterial angiography is the study of choice for a typical TIA. On many occasions, however, the clinical presentation of a TIA is atypical. For example, postural hypotension, transient visual disturbance not of ischemic origin, tingling in the arms due to cervical spondylosis, all simulate a TIA and non-invasive evaluation of the carotids is valuable when the index of suspicion is low. Duplex sonography is an excellent diagnostic study to rule out the presence of significant carotid artery disease. In practice, therefore, this is one of the commonest indications for referral for duplex evaluation.

3. To monitor progression of known disease

Prevous evaluation by duplex techniques or angiography have revealed a population with nonsignificant disease, especially on the nonsymptomatic side. Previous studies have reported that carotid disease inexorably progresses in most patients[9] and that surgical intervention is warranted for patients who become symptomatic or in whom stenosis exceeds 80%.[10]

4. Follow-up postendarterectomy

The incidence of restenosis after carotid endarterectomy is reported to be 12%. Cantelmo advocated follow-up scans at 1, 3, and 12 months after surgery.[11]

5. Prior to major surgery

Patients with severe stenosis of the carotid arteries may develop a stroke because of hypotension during major vascular surgery such as coronary bypass. Kratchmer reported a 17% incidence of stroke in patients undergoing major cardiovascular surgery when the stenosis exceeded 60%.[12] Duplex techniques are entirely adequate to exclude such significant lesions.

Normal Duplex Scan

An ultrasound image of a normal carotid bifurcation is shown in Figure 1 with the Doppler waveforms superimposed. In the normal common carotid artery, the red cells are moving at a single and uniform velocity during systole. The systolic waveform shows virtually a single line without spectral spread. The diastolic downstroke is characterized by a frequency spread due to viscous drag on the cells nearest the wall, thus, the thickening of the time-velocity envelope (Figure 1). The maximum peak velocities are recorded from the internal carotid artery which has high diastolic flow associated with low impedance in the cerebral vessels. The maximum normal velocity in the internal carotid artery is less than 110cm/s with a wide variation between normals. The maximum velocity (V) of the internal carotid is compared with that

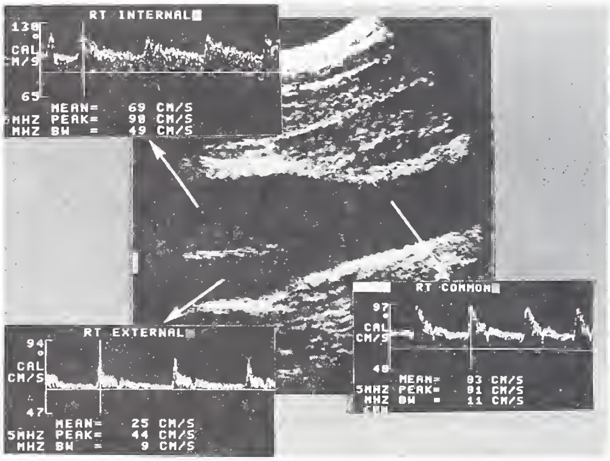

Figure 1

Montage to show carotid bifurcation with corresponding Doppler waveforms. The waveforms are time-velocity spectra with velocity of blood on the vertical axis and time on the horizontal axis. The clear "window" under the waveform indicates that all cells are moving at the same velocity. A marker on the peak velocity indicates that the maximum velocity with the common carotid during systole is 91 cm/s. Note that there is moderate diastolic flow. The right internal carotid waveform also demonstrates a normal clear window under the time-velocity spectrum and there is high diastolic flow. This indicates a low impedance cerebral circulation. In contrast, the waveform in the right external carotid waveform demonstrates low diastolic flow indicating a high impedance. This difference in waveform helps to differentiate these two vessels when doubt exists.

in the common carotid (V_c). The ratio V_i/V_c should be less than unity.[13] The external carotid has very low diastolic flow which serves as a good way to differentiate it from the internal carotid artery.

Nonsignificant Disease

Minimal lesions, such as an atheromatous plaque, may give rise to turbulence with loss of laminar flow characterized by filling in of the window of the time-velocity envelope. This is termed "spectral broadening".[14] (Figure 2.)

Another way of making the diagnosis of nonsignificant stenosis is by using the ratio of the peak velocity in the internal carotid artery compared to the peak velocity in the common (V_i/V_c).[13] This ratio is used because of the wide difference in the peak velocity in the internal carotid in different individuals. Thus, the internal carotid velocity is used as an individual caibration. Increased velocity in the internal carotid implies a narrowing of the vessel. (Figure 3) The stenosis is roughly linearly proportional to the increase in ratio up to a 50% stenosis. A 1.5:1 ratio implies a stenosis of 25% (Figure 3) and a 2:1 ratio, approximately a 50% lesion. More severe lesions cause a loss of this relation due to turbulence.[13]

Significant Stenoses

Significant stenoses refer to lesions causing a flow reduction exceeding 50% and significant for potential surgical correction when exceeding 80%. In this situation, the flow velocity increases beyond the normal range and exceeds 110 cm/cm in the internal carotid artery[15] with a returned Doppler shift exceeding 4 kHz (using a 4.5 kHz insonating frequency). The frequency shift is approximately proportional to the degree of stenosis. Thus, a Dopper shift of 5-6 kHz corresponds to a moderate stenosis of around 70% whereas a severe stenosis of 90% results in a Doppler shift of 7-8 kHz or a velocity exceeding 200 cm/s. (Figure 4.) A confirmatory indicator of a severe distal stenosis is the waveform seen proximally in the common carotid artery in Figure 4. The waveform is of low amplitude with little diastolic flow suggesting high pulsatility in the common carotid compared with the normal waveform seen in Figure 1.

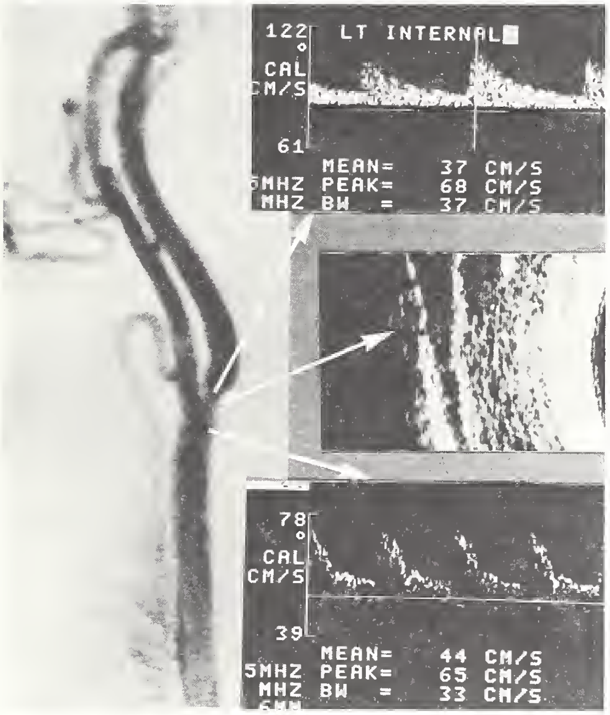

Figure 2

Montage of angiogram with slight stenosis at the origin of the internal carotid. The common carotid waveform is normal. A small plaque on the vessel wall giving rise to turbulence is seen on the ultrasound image. This results in "spectral broadening" which causes filling in of the normal clear "window" under the time-velocity waveform. Turbulence results in red cells moving at all different velocities and hence causes this spectral spread.

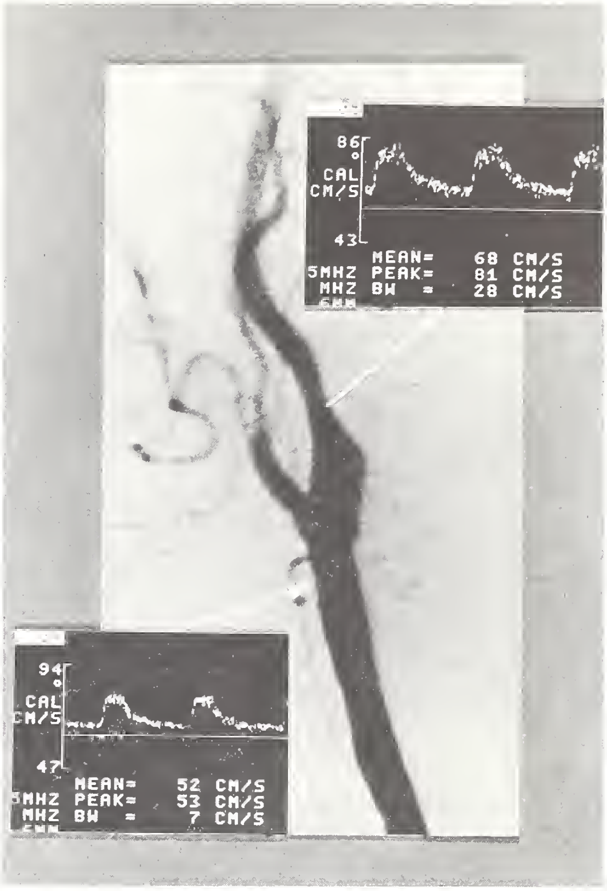

Figure 3

Montage of angiogram and carotid waveforms. There is a slight, nonsignificant narrowing of the internal carotid. Note this increases the velocity of blood in the internal compared with the common carotid. The peak velocity in the internal is 81 cm/s compared with 53 cm/cm in the common carotid yielding a V_i/V_c ratio of 1.6 corresponding to a nonsignificant 30% stenosis.

Occlusion

The diagnosis of a total occlusion can be made most reliably by Doppler which shows no evidence of arterial flow. The proximal artery shows very low flow with no diastolic component. (Figure 5a.) In addition, there is usually reversal of flow in the periorbital arteries. Nor-

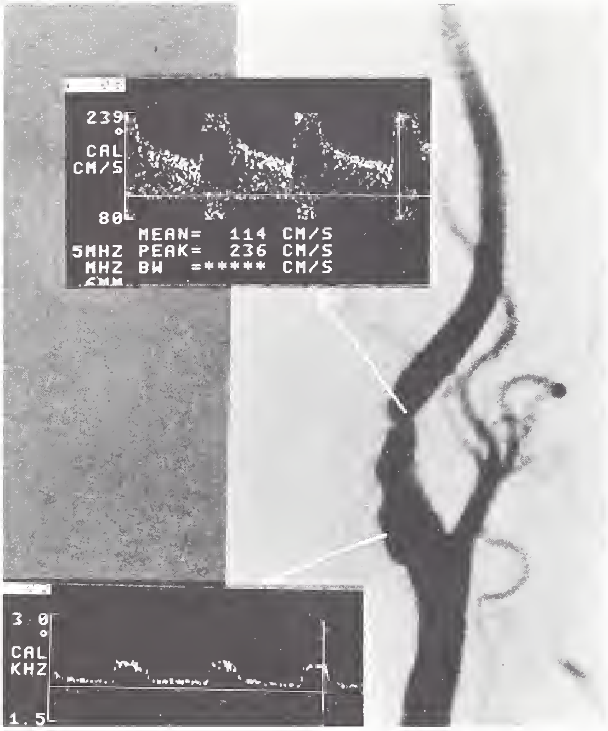

Figure 4

Montage to show low amplitude flow in common carotid artery proximal to a severe stenosis. At the stenosis in the internal carotid, there is a high velocity jet exceeding 236 cm/s with spectral broadening. This indicates a severe stenosis of at least 90%.

mally, the direction of flow in the periorbital arteries, (the supraorbital and supratrochlea) is out of the cranium and hence towards the transducer when applied around the eye. When the pressure in the intracranial vessels is greatly reduced by a severe stenosis or occlusion, the direction of flow usually reverses since the cranial contents are supplied by collateral flow from the extracranial vessels. Thus the directional defining capability of the Doppler equipment can be used to diagnose collateral flow (Figure 5b.) When reversed flow is demonstrated, the source of the collateral flow can be determined by compressing the facial and superficial temporal artery. If these are the feeding vessels, compression causes a reversal of flow although at greatly reduced amplitude (Figure 5b.) It should be appreciated that periorbital Doppler itself, however, is an insensitive means of detecting carotid artery disease and only becomes positive when there is very severe stenosis or occlusion.

Reports in the literature indicate that Duplex techniques are most vulnerable in differentiating a complete occlusion from a 95%+ stenosis with very low flow.[16] Since the surgical treatment of these two conditions is different, an angiogram is warranted if such patients are surgical candidates. Despite reports of difficulties in diagnosing carotid occlusion, the criteria of absent internal carotid flow with reversed flow in the periorbital vessels, and low amplitude signals proximal to the occlusion make the diagnosis.

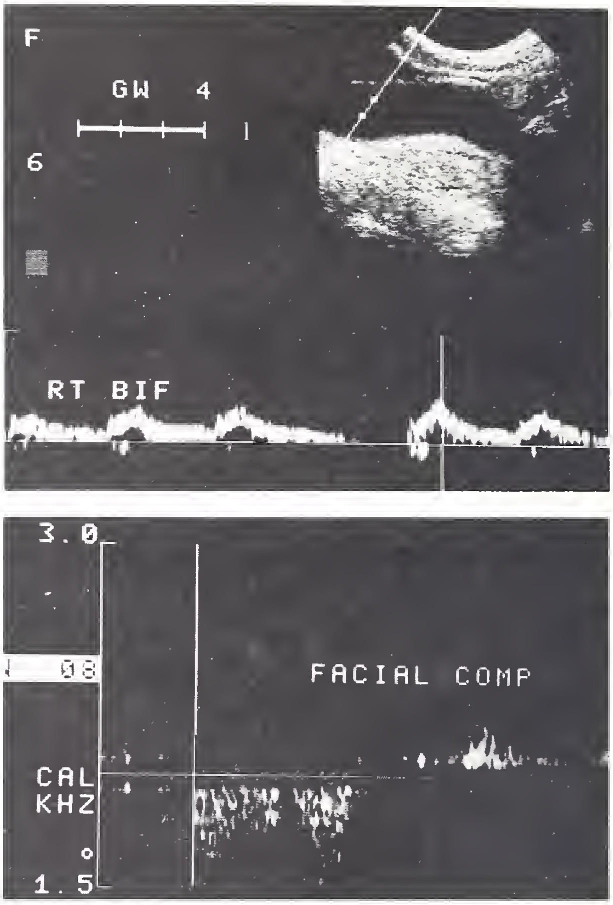

Figure 5

a. Very low flow in common carotid artery proximal to a complete occlusion with absent flow in the internal carotid. b. Doppler waveform in the supra-orbital artery showing flow away from the transducer (below the zero line). Compression of the facial artery causes this flow direction to reverse. Note that the forward flow is of low amplitude. This indicates that the cranial contents are supplied through collateral branches of the facial artery.

Atheromatous Ulcers

For the diagnosis of atheromatous ulcers, angiography is considered to be the diagnostic method of choice with greater sensitivity than ultrasound. However, in a more recent paper, 90% of ulcers were detected by ultrasound.[17] A large ulcer is shown in Figure 6 imaged by ultrasound and angiography.

Recent studies have focused on the plaque appearance rather than purely the degree of flow reduction. The occurrence of intraplaque hemorrhage is a common initiator of TIA's and intracerebral embolization. The appearance of inhomogeneous plaque suggests intraplaque hemorrhage and is much more common in symptomatic than in nonsymptomatic patients.[18] A sensitivity of 91% and a specificity of 65% in the diagnosis of intraplaque hemorrhage has been reported by Reilly et al.[19] This lower specificity is due to the presence of other structures including lipid, cholesterol and protein composites.

Conclusion

In conclusion, noninvasive evaluation of the carotid

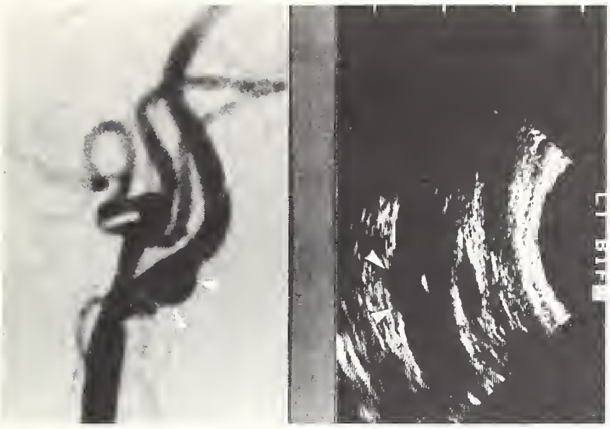

Figure 6

Large shallow ulcer seen on the angiogram and similar appearance on the ultrasound image (arrowed).

system using duplex equipment is a reliable technique for the initial screening of patients with clinical suspicion of disease. It can be used to triage patients before angiography, and to follow longitudinally for nonsymptomatic disease or after endarterectomy. In the immediate future, the introduction of color-coded Doppler will facilitate the perception of vascular stenoses although the criteria described herein will continue to be used to quantitate severity.

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Preventing Complications of Vesicoureteral Reflux

DAVID T. MININBERG, M.D.

Vesicoureteral reflux (VUR) and reflux nephropathy are important etiologic factors in renal scarring and renal insufficiency in children. Voiding cystourethrography, static cystograms, and cystoscopy can be used to document suspected VUR. Low-grade reflux (grades 1 and 2) can often be managed with long-term antibiotic prophylaxis. Recurrent or breakthrough infection, high-grade reflux, or persistent or worsening reflux warrant surgical correction. Early intervention is mandatory to prevent renal scarring, retarded renal growth, hypertension, and chronic renal failure.

The association of vesicoureteral reflux (VUR) and urinary tract infection with the development of renal scarring was first described in 1960.[1] Although there has been extensive clinical experience with this problem and a voluminous literature exists, there are still significant areas of controversy concerning reflux.

Prevalence

The prevalence of VUR in the general population is unknown, since most data come from children undergoing urologic investigation to determine the cause of persistent recurrent urinary tract infection. Because such investigation is not universally undertaken, the information available is clearly an underestimate of undetermined magnitude. The prevalence of VUR in the uninfected population surveyed in the world literature is between 0.4% and 1.8%.[2] Table 1 summarizes data collected in 7 separate studies of school-aged children with screening bacteriuria.[3-9] Of the 1172 (1.9%) found to have bacteriuria, VUR was detected in 168 (14%).

The prevalence of VUR appears to be higher in 2 subgroups of the population: neonates with documented urinary tract infection, and siblings of other first-degree relatives of individuals with known VUR. The prevalence of the condition in infected neonates has been reported to be as high as 57% (Table 2).[10,11]

It should also be remembered that only children with documented urinary tract infections underwent cystourethrography. The prevalence of vesicoureteral reflux in the uninfected population, and therefore in the entire population, is unknown. Present techniques for documenting VUR are costly, involve radiation exposure, and cannot be considered screening procedures; the overall prevalence of VUR will, therefore, probably remain unknown.

Table 1
PREVALENCE OF VUR IN SCHOOLCHILDREN WITH SCREENING BACTERIURIA

Study	*Patients' Ages (yrs)*	*# Patients*	*# with Bacteriuria (%)*	*# with VUR (%)*
Kunin et al[3] (1964)	5-9	3887	42 (1.1)	12 (29)
Newcastle Group[4] (1975)	4-18	13,464	256 (1.9)	54 (21)
Savage et al[5] (1973)	5	5217	109 (2.1)	36 (33)
Asscher et al[6] (1973)	5-11	8722	145 (1.7)	34 (23)
Meadows et al[7] (1969)	5-14	1026	10 (1.0)	2 (20)
Silverberg et al[8] (1973)	6-14	23,427	546 (2.3)	18/83 (22)*
Kelly et al[9] (1969)	5-14	3902	64 (1.6)	12/58 (21)*
Totals		59,645	1172 (2.0)	168 (14)

* Patients with VCU performed.

Table 2
PREVALENCE OF VUR IN NEONATES WITH SCREENING BACTERIURIA

Study	*# Patients*	*# with Bacteriuria (%)*	*# with VUR (%)*
Abbott[10] (1972)	1460	14	8 (57)
Winberg et al[11] (1974)	47	47 (100)	22 (47)
Totals	1507	61 (4)	30 (49)

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Vesicoureteral reflux is a congenital lesion, in some instances familial and inherited. Six sets of identical twins with reflux in each partner of the twinship[12-17] and 300 families with 2 or more family members having VUR[18-39] have been reported. The prevalence ranges between 8% and 34% in those families for which data are available. This is significantly higher than the prevalence of VUR in the general population, based on current knowledge.

The 2 genetic mechanisms most often proposed are polygenic multifactorial inheritance and autosomal dominant inheritance with incomplete or variable penetrance. Bailey and colleagues[39] propose that the major histocompatibility locus (HLA) is possibly in a linkage disequilibrium with another gene or genes. This altered linkage or its clinical expression may be responsible for the occurrence of reflux.[39-41]

Classification

The adoption of the International Classification of vesicoureteral reflux has facilitated discussion of the diagnosis, therapy, and results in different series and reports (Figures 1,2). This classification, based on the extent of reflux and the degree of ureteral dilatation and/or caliectasis, will be used throughout this discussion. Renal

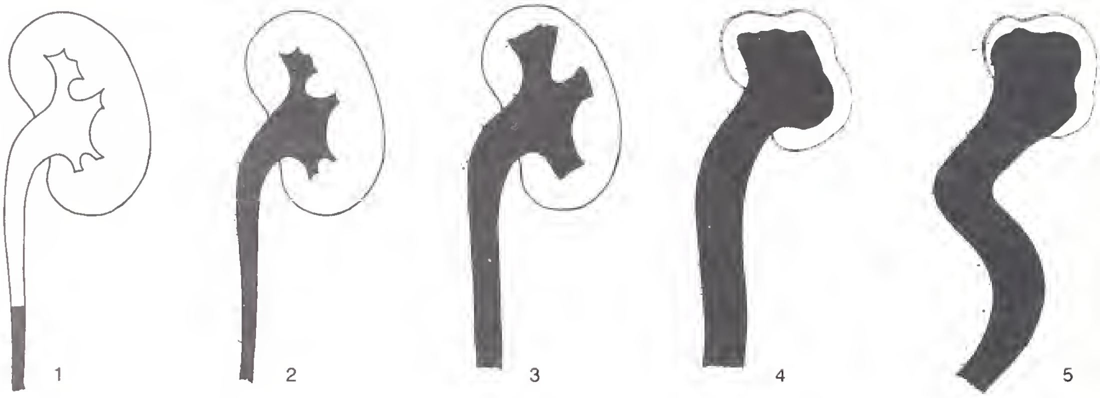

Figure 1
International classification of vesicoureteral reflux. Shaded areas signify level of refluxed urine.

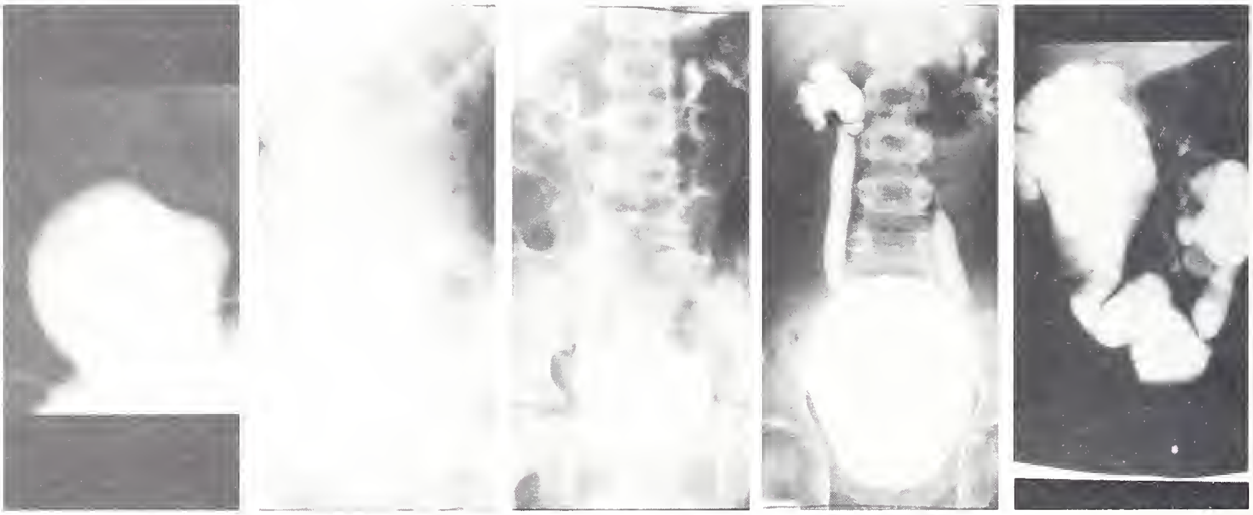

Figure 2
Voiding cystourethrograms demonstrating classes 1-5 of vesicoureteral reflux.

scarring resulting from the combination of VUR and urinary tract infection is classified as minimal, moderate, severe, or progressive.

Diagnosis

The most accepted method for detecting renal scarring has been intravenous urography (IVP). Unfortunately, this method will often fail to detect early or minor renal scars. Its sensitivity can be enhanced by including tomographic views, although this significantly increases the amount of radiation to which patients are exposed and requires a level of patient cooperation often beyond the ability of children. Sonography may be used to demonstrate renal scarring but is also somewhat limited in terms of disgnostic definition as well as patient cooperation. The most recent technology for diagnosing renal scarring is isotope renal scanning, using 99MTc-DMSA. This method correlates well with intravenous urography yet delivers a fraction of the radiation exposure.[42-44]

Morbidity

The short-term or immediate morbidity due to vesicoureteral reflux includes essentially those symptoms associated with the acute onset of upper urinary tract infection: fever, general debility, and a variable amount of pain. In some instances septicemia may be a more than transient event, with consequent increased morbidity. In most cases the immediate problem is dealt with by instituting appropriate antibiotic therapy, which will usually bring about prompt resolution of symptoms. This appealing scenario unfortunately does not preclude the development of long-term sequelae.

The most significant long-term sequelae resulting from VUR include renal scarring, impedance of renal growth, hypertension, and chronic renal failure.

Infection, VUR:

Relationship to Renal Scarring

The relationship of VUR, with or without infection, to renal scarring and reflux nephropathy is a controversial issue. Abbott[10] failed to demonstrate scarring in the kidneys of 8 neonates with documented VUR. In a similar survey, Drew and Acton[45] showed that 27 neonates with reflux in a group of 12,942 had no evidence of renal scarring. This concurs with the report of Bergstrom and colleagues,[46] who found no renal scarring in 80 neonates studied after an initial urinary tract infection.

Other large populations surveyed revealed the incidence of renal scarring in association with VUR to be approximately 34%. These series had some individual variation (Table 3).[3-6,38,47,48] Where details are available, it is evident that renal scarring becomes more prevalent with increasing age of the affected child.[44,47] This would explain the paucity of cases of renal scarring in neonates.[45,46] There are, however, some data to the contrary. In the series of Bailey[49] from New Zealand, 31 infants were reported with significant VUR. This group of children did poorly; 5 died, 10 went on to develop hypertension, and 2 developed chronic renal failure.

Table 3

VESICOURETERAL REFLUX AND RENAL SCARRING

Study	*# Patients*	*# Patients Refluxing (%)*	*# Reflux with Renal Scars (%)*	*Renal scars No Reflux*
Kunin et al[3] (1964)	42	12 (29)	5 (42)	?
Newcastle Group[4] (1975)	256	54 (21)	18 (33)	21
Savage et al[5] (1973)	109	36 (33)	21 (58)	5
Asscher et al[6] (1973)	145	34 (23)	14 (41)	10
Bellinger & Duckett[47] (1984)	618	618 (100)	177 (29)	5
Goldraich[38] (1984)*	284	210 (74)	83 (40)	?
Winter et al[48] (1983)*	4000	41 (1)	27 (66)	
Totals	5454	1005 (18)	345 (34)	

* Renal units.

The role of repeated infection in the development of renal scarring in individuals with reflux is unclear, but obviously important. The association between urinary infection and progressive renal scarring in the absence of reflux is even more complex. Renal scarring apparently takes at least 8 months to develop to a point where it can be detected by presently available diagnostic means.[50] It is tempting to postulate previous episodes of undetected reflux, but this hypothesis obviously cannot be proven. An alternative explanation could be that the period of observation was not long enough to detect reflux.

There is good evidence in the literature that renal scarring can progress after VUR has resolved spontaneously or through successful medical or surgical intervention. In prospective studies of schoolgirls, reflux nephropathy and scarring rarely occurred in kidneys that were normal at the time of initial evaluation.[51,52] Smellie and coworkers[53] found new scars appearing in 10 of 233 previously normal kidneys. Active reflux and current or remote urinary tract infection were discovered in all cases. These authors also tabulated other reports and found that a total of 83 children out of 17,290 (4.8%) had fresh scarring in a previously normal kidney. In all cases but one this event was accompanied by VUR and a positive history of urinary tract infection.

Dunn and Smith[54] found that 22 of 1434 children (15%) developed progressive renal scarring while being treated nonsurgically for reflux grades 4 and 5. Winter and associates[48] found 27 new or progressed scars in 41 children (66%) with VUR treated episodically for urinary tract infections. They additionally identified 7 of 15 children with surgically corrected VUR who continued to have progressive renal scarring. This last finding suggests an immune-mediated mechanism may be responsible for the progression of reflux nephropathy scarring even after apparently successful therapy.

Similarly, Elo and others[55] found that 10 of 40 girls (25%) successfully operated on for VUR had progressive renal scarring. This was also true in 66% of patients reported by Filly and colleagues.[56] In these last 3 studies new episodes of urinary tract infection were absent; this fails to support the concept that infection is necessary for progressive renal scarring.

Resolved vesicoureteral reflux leaves evidence of its existence in the configuration of the ureteral orifice. Lyon and co-workers[57] found that an abnormal cystoscopic appearance of the ureteral orifice(s) correlated well with VUR and renal damage.

The postulate that concurrent VUR and urinary tract infection are necessary for the development of reflux nephropathy was stated by Bailey and Lynn,[58] who found an equal male-to-female ratio in a group of patients with renal nephropathy in end-stage renal failure requiring dialysis and/or transplantation. Similar findings have been reported by Winberg.[59] These ratios are in contrast to the 3:1 female-to-male ratio for childhood urinary tract infection. Conflicting data regarding this point have been obtained in experimental work done using the piglet. Ransley and Risdon[60,61] were able to produce reflux nephropathy in the piglet with induced VUR only if they simultaneously infected the obstructed system. However, if they significantly raised the intravesical pressures, reflux nephropathy could be produced by sterile VUR.[62] The latter situation was also observed by Hodson.[63] These observations introduce an additional variable, that of increased intravesical pressure, into possible etiologic mechanisms resulting in VUR.

Effects on Renal Function

In addition to the imaging changes demonstrating scarring with possible progression, reflux nephropathy is characterized by some loss of function in the affected kidneys. In a group of 207 schoolgirls with urinary infection screened from a population of 13,369, Jones and others[64] found that the GFR in girls with scarred kidneys (99 + 24) was significantly less than in those with normal kidneys (119 + 18). In addition, those with VUR had GFRs significantly lower (103 + 21) than those of the normal group (120 + 20). These findings are supported by Torres and colleagues,[65] who found that the GFR was significantly decreased in the reflux nephropathy group.

In addition, they demonstrated a diffuse glomerulopathy in patients who were proteinuric, whereas those without proteinuria had only mesangial changes. This suggests a progressive glomerulopathy. Similar observations by other groups further support this concept.[66-73]

There are also several cases of unilateral reflux nephropathy in which the contralateral or "normal" kidney also had progressive glomerulopathy leading to end-stage renal failure. The crux of this issue lies in the ability to detect minimal changes in the so-called normal kidney. The nature of the glomerulopathy is diffuse, and renal biopsy is not a reliable means of making the diagnosis.[67]

Changes in GFR in reflux nephropathy are more pronounced than changes in the serum creatinine. In a group of 210 children in Brazil, Goldraich and co-workers[44] found that although 41% of them had reflux nephropathy, only 28% had any functional renal impairment. This emphasizes the breadth of the spectrum of reflux nephropathy.

It also highlights one of the dilemmas in analyzing functional data. The extent of functional impairment detected depends, in large measure, on the amount of compensatory hypertrophy in the unaffected or minimally affected kidney. This will vary with time and circumstances, particularly in the growing child. Therefore, the true functional impact of reflux nephropathy is unknown and probably underestimated.

An alternative explanation for the glomerulopathy seen with reflux nephropathy is that the lesions are secondary to the resultant overperfusion of the "normal" or unscarred kidney. This would be consistent with experimental work done by Hosteller and associates.[74]

It has been shown that successful surgical correction of VUR can stabilize renal function[75] and even result in improvement, particularly in the GFR.[76] Mundy and colleagues[76] have suggested that the improvement in function is the result of reversal of the adverse effect on renal blood flow by reflux. This theory has received experimental support in the findings of Orr and co-workers[77] and Helin and others.[78] Both these groups showed that unilateral reflux interferes with renal blood flow to the affected kidney.

Effects on Renal Growth

The physical growth of kidneys subjected to untreated reflux is retarded. This is true of both the obligate growth under the control of growth hormone[79] and compensatory growth under the influence of renotropin.[80-82]

Obligate renal growth is characterized by hyperplasia and can be monitored by changes in DNA activity.[83,84] Compensatory growth can occur in kidneys subjected to reflux after the reflux has been corrected, either medically or surgically. Smellie and associates[85] found satisfactory growth in 100 of 111 kidneys in patients with reflux that had been treated with long-term prophylactic antimicrobials. The 10 kidneys that failed to grow had become reinfected. Seven had scarring and 4 were subjected to gross reflux.

Kelalis[86] has reported resumption of renal growth after reflux has been eliminated. Again, the role of infection is unclear; Lyon[87] and Redman and colleagues[88] separately reported a subnormal growth rate in kidneys subjected to reflux without infection.

McCrae and co-workers[89] and Willscher and others[90] have shown accelerated renal growth following successful ureteral reimplantation. The small, shrunken kidney of renal nephropathy has been shown to grow after successful reimplantation of its refluxing ureter.[91] One reasonable explanation for these observations is that after successful reimplantation, even if bladder bacteriuria persists further pyelonephritis is rare, because reflux of infected urine is eliminated.

Hypertension

Hypertension presents as a late manifestation of reflux nephropathy. It has been estimated that the incidence among adolescents and young adults is 1.2%.[92] Smellie and co-workers[85] found hypertension in 20% of children with scarring and reflux nephropathy. Hypertension was the presenting complaint in 29 of 145 young adults with reflux nephropathy.[93] In a series of 141 patients with VUR operated on at least 10 years previously, Wallace and associates[94] detected hypertension in 18 (13%). In a series of 102 patients with VUR followed over a 5- to 18-year period, Lenaghan and colleagues[95] found 10 (10%) with hypertension. These patients had been treated medically, with a regimen of antibiotic prophylaxis and multiple consecutive voiding (double or triple voiding). Torres and associates[96] studied a population of 67 young adults with VUR. At the time of diagnosis, 23 of 67 (34%) had hypertension. Of those 23 hypertensive patients, 19 had bilateral renal scarring and 3 had unilateral scarring. These data led Torres's group to question the value of nephrectomy as a cure for hypertension, since the scarring and underlying disease process are usually bilateral.

The search to identify the potentially hypertensive individuals in the population of renal nephropathy patients has focused on plasma renin activity (PRA). Dillon,[97] Gerdts and associates,[98] and Savage and co-workers[99] have demonstrated a clear relationship between significant hypertension associated with renal nephropathy and elevated PRA. Dillon and Smellie[100] have additionally shown that the PRA in the hypertensive group is greater than in both the normotensive group and controls. In a group of 33 patients with renal vein renin ratios greater than 1.5:1 (side-to-side ratio), the cause for hypertension was well localized. In 22 of the 33, operative intervention was undertaken. Fourteen were cured, and the other 8 showed a significant improvement in the degree of hypertension. Monitoring serum PRA levels may, then, be a useful means for following children with renal nephropathy and scarring.

Treatment of VUR

The above review attempts to put the main issues of urinary tract infection and VUR into perspective and to establish the basis for a rational therapeutic approach to this problem. In view of the potentially serious complications of VUR, particularly if untreated or inadequately treated, prompt diagnosis is mandatory. Based on the well-established association between urinary tract infection and reflux, many practitioners feel that all children should undergo an imaging evaluation at the time of their first documented urinary tract infection. Use of sonography and isotope cystography will minimize radiation exposure to the child. Standard voiding cystourethrograms or intravenous urograms can be used to supply more detail where warranted.

Most practitioners would agree that investigations should be undertaken after an initial course of antibiotic therapy. In cases where the urinary tract cannot be sterilized after a reasonable trial, the evaluation should be undertaken to ascertain what about that particular case is unusual.

The initial therapeutic step taken should be culture-specific antibiotic therapy. Once the acute infection has been eradicated, the patient should receive a prolonged (3- to 6-month) period of prophylactic antibiotic therapy. Following this, the initial diagnostic studies are repeated. If the patient is free of infection and the reflux has resolved without leaving changes in the upper tracts, the program may be considered a success, but the patient will require follow-up urine cultures at regular intervals. Although the overall prognosis is excellent, the possibility of renal scarring developing in the future cannot be completely ignored.

This program allows reasonable time for a trial of control while hoping for spontaneous resolution of the reflux. This tends to occur in about 50% of ureters if sufficient time is allowed.[101-103] The spontaneous resolution rate is much greater for grades 1 and 2 reflux than for grades 3 to 5. Therefore, if the prophylactic program is succeeding, but low-grade (1,2) reflux persists, a prolonged period of therapy is in order.

In cases of breakthrough infection during prophylactic antibiotic therapy or worsening reflux following the period of prophylaxis, surgery is indicated. Surgery is also warranted in cases of progressive deterioration of the upper urinary tract. The aims of surgery are to correct reflux and restrict any future urinary tract infections to the bladder.

An additional benefit of successful ureteral reimplantation is the elimination of the obstructive element of the VUR. Refluxed urine interferes with urine normally being peristalsed down the ureter, causing a functional obstruction. The discussion on renal growth highlights the fact that the reflux-affected kidney will undergo accelerated growth following correction of the reflux. This further stresses the importance of undertaking prompt surgery in those situations in which nonsurgical therapy is not entirely successful.

The aim of surgical correction of reflux is to convert the anatomy of the refluxing vesicoureteral junction into a more normally functioning unit. The essence of the problem is illustrated in Figure 3. The refluxing ureter has a shorter intramural passage than the normal ureter.

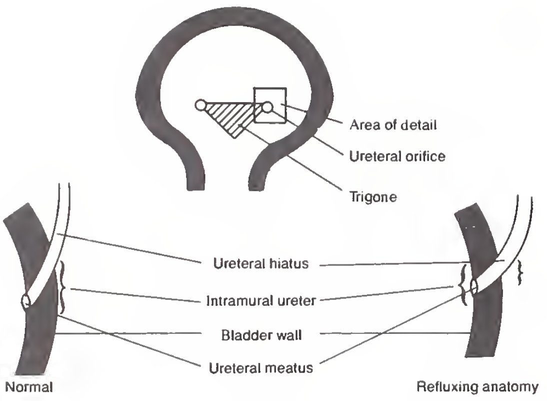

Figure 3
Anatomy of ureterovesical junction.

The angle of entrance into the bladder at the refluxing ureteral hiatus is also noted to be less acute. These factors combine to provide less detrusor muscle behind the uerter with resultant deficiency of the valvelike action of the ureterovesical junction. Successful surgical correction results in more detrusor muscle behind the ureter with a resultant anti-reflux function of the ureterovesical junction.

Many operative techniques have been devised to correct reflux. Each has attempted to meet the fundamental requirements set forth by Paquin: (1) a tension-free anastomosis between the ureter and bladder; (2) a submucosal tunnel approximately 5 times as long as the diameter of the ureter; (3) firm support for the intravesical ureter by the underlying bladder muscle; and (4) positioning of the ureteral orifice on the floor of the bladder to limit its movement during bladder filling.[104] These criteria are adequately met by a number of operative procedures.[105-110] The details of these procedures are beyond the scope of this article and may be found in the enumerated references.

The overall results with these various techniques are excellent in experienced hands. A broad overview and summary compilation of published large series of patients leads to the conclusion that the success rate of surgery for grades 1 and 2 reflux is 98% to 100%, for grade 3, 95% to 99%, and for grades 4 and 5, 50% to 60%.[111-115]

Although controversial issues remain in the diagnosis and therapy of VUR, this review should facilitate the development of a rational program of therapy based on currently known and accepted facts.

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Important Advances in Clinical Medicine

Epitomes of Progress—Neurosurgery

The Scientific Board of the California Medical Assocation presents the following inventory of items of progress in neurosurgery. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoriative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in neurosurgery that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Neurosurgery of the California Medical Association and the summaries were prepared under its direction.

Early Versus Delayed Operation in Subarachnoid Hemorrhage

Subarachnoid hemorrhage from a ruptured intracranial berry aneurysm remains a major source of morbidity and mortality in adults, afflicting patients in their most productive years. Many die before reaching a hospital, while others succumb to rebleeding and vasospasm after their original hemorrhage.

Rebleeding is most frequent in the first three weeks following aneurysmal rupture—its peak being at day 1—and kills and disables an additional 17% of patients reaching referral centers. Symptomatic cerebral vasospasm occurs in about a third of the patients between day 3 and day 21 and causes severe stroke or death in half of these. Traditionally, definitive surgical treatment (clipping of the aneurysm) has been delayed to avoid inducing or aggravating vasospasm in the acute state and to allow the cerebral swelling that follows the initial rupture to resolve. Because patients die while awaiting an operation, however, there has been recent interest in earlier operative intervention. Early surgical intervention effectively decreases the incidence of rebleeding and allows a more aggressive medical management of vasospasm using hypertension and hypervolemia without the risk of another rupture. It also allows the removal of spasmogenic clot from the basal cisterns, and it reduces medical complications related to prolonged bed rest and antifibrinolytic therapy.

A recently completed copperative study addressed the problem of management morbidity and mortality with early versus delayed surgical treatment. Preliminary findings suggest that an early operation may improve overall outcome in most patients. In good grade patients, the surgical mortality does not significantly change if an operation is done early. Clearly, more patients die while waiting for a delayed surgical procedure than die as a result of increased risks of an early one. Furthermore, early operation does not increase the incidence or worsen the outcome of symptomatic vasospasm. Only patients with severe clinical vasospasm at the time of presentation appear to benefit from cautious delay of the operation until symptoms have cleared.

It is foreseeable that an increased awareness of this entity in the general population will lead to a much earlier recognition of the disease through its warning symptom—that is, sentinel leak—and early surgical repair can be carried out before the devastating effects of major aneurysmal rupture occur.

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Chronic Benign Pain Management

Chronic benign pain is estimated to affect as many as 20 million people in the United States, representing an emormous loss of productivity, large medical expenses and considerable suffering for the persons so affected. A multidisciplinary team approach to pain management emphasizes an accurate intial diagnosis and treatment directed at reducing drug dependence and increasing functional capabilities. Techniques used include behavioral modification, physical therapy, transcutaneous electrical stimulation, nerve blocks, hypnosis, biofeedback and acupuncture, among others.

In general, neurosurgical therapy for chronic benign pain should be used only after a thorough trial of treatment by a multidisciplinary pain management team. Two recent neurosurgical procedures for treating chronic benign pain include electrically stimulating deep brain structures and placing lesions in the dorsal root entry zone of the spinal cord. The brain stimulation technique is based on results of studies in animals that showed powerful pain inhibitory pathways descending from the periaqueductal grey region of the brain stem and from the thalamus to the dorsal horn region of the spinal cord. In the animal studies, analgesia from periaqueductal stimulation appeared to be related to release of naturally occurring opiatelike substances, the so-called endorphins. The neurotransmitters involved in pain relief for lateral thalamic stimulation are unknown. To treat chronic pain in humans, these pain-inhibiting systems may be electrically activated by stereotactic placement of stimulation electrodes in either brain site. Pain may be relieved in 65% to 70% of patients by the brain-stimulating technique, with few complications and without interference with normal neurologic function. Excellent results have been obtained in patients with chronic back and leg pain after unsuccessful spinal operations. Good results have also been obtained in patients with chronic pain due to trauma, postherpetic neuralgia, anesthesia dolorosa and certain nerve entry injuries.

The technique of placing lesions in the dorsal root entry zone is based on studies that showed neuronal hyperactivity in the dorsal horn of the spinal cord following deafferentation. Made by either a radio-frequency electrode technique or with a laser, these lesions have relieved chronic pain in a high percentage of patients following spinal cord injury and avulsion of the brachial or lumbar nerve plexuses. Because this technique is used for treating pain following deafferentation, pain relief may be accomplished without further loss of neurologic function.

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Intraoperative Monitoring With Ultrasonography

Various methods have been used in the past to locate intraoperatively lesions of the central nervous system. These techniques have usually required that the neurosurgeon transfer static information from diagnostic imaging studies to the operative situation. By applying ultrasonography to neurosurgical procedures, it has become possible to utilize data as it is generated (realtime) in localizing lesions.

The usual method of scanning for intracranial lesions is to first scan transdurally with a low-frequency transducer. In this way, the operator may become oriented by identifying structures such as the ventricles and the falx cerebri. Once the dura is opened, the lesion may be further characterized by using transducers that provide higher resolution. When scanning the intraspinal contents, the surgical wound is filled with sterile saline that serves as a coupling agent. Using a high-frequency transducer, scanning is carried out in a systematic manner noting the position of structures such as the central canal. Using the scanner's computer, the depth and the size of intracranial and intraspinal lesions may be determined.

Intraoperative ultrasonography enables a surgeon to readily identify lesions with high echogenicity, such as solid tumors, hematomas, displaced bone and missile fragments, and those with low echogenicity, such as solid tumors, hematomas, displaced bone and missile fragments, and those with low echogenicity, such as abscesses, syringomyelic cysts and enlarged ventricles. Excision, aspiration, biopsy or cannulation may then be done and monitored under ultrasonic control.

Except in infants with an open anterior fontanelle, an opening in the intact calvarium or the spine must be created to accommodate the ultrasonic probe. As intraoperative ultrasonography continues to be widely used in neurosurgical procedures, it is anticipated technology will provide probes requiring smaller bone openings.

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Diagnosis and Surgical Management of Cervical Syringomyelia

Cervical syringomyelia is a cystic dilation that develops in the cervical spinal cord, typically originating in the region of the vestigial central canal. Clinically, syringomyelia produces pain and progressive sensory loss to pain and temperature modalities in the upper extremities and upper cervical-thoracic region and with time can lead to a complete loss of spinal cord function below the lesion. The natural history of syringomyelia is highly variable. While some patients' conditions improve or stabilize without surgical therapy, others deteriorate even with the most aggressive intervention. While the cause of cervical syringomyelia is unclear, it commonly develops in patients with the cerebello-medullary malformation syndrome (Arnold-Chiari syndrome) with obstruction of the outlet foramina of the fourth ventricle. In some cases, no causative factors can be identified. Posttraumatic syringomyelia can develop in patients with spinal cord injury, typically in those with complete traumatic spinal cord transection in the thoracic region. In these cases, indolent progressive loss of sensory and motor function above the level of spinal cord transection may indicate the development of a syrinx. Occasionally intramedullary spinal cord tumors can also be associated with cystic accumulations of fluid within the spinal cord that can mimic the syndrome of syringomyelia.

The neuroradiologic diagnosis of syringomyelia has been greatly facilitated by the development of magnetic resonance (MR) imaging, in that MR imaging provides a complete visualization in the sagittal plane of the cervical cord, craniocervical junction and related regions. Also, associated hydrocephalus, cerebellar tonsillar and posterior fossa abnormalities can be visualized with their relationship to the cervical spinal cord. Operative strategies may be planned based on the MR imaging data. In addition, its use avoids invasive procedures such as myelography or cisternography and it can be done on an outpatient basis.

A large number of operations have been advocated for treating syringomyelia, including posterior fossa decompression with or without plugging of the communication of the fourth ventricle with the central canal of the spinal cord, syringostomy with syringosubarachnoid shunting, terminal ventriculostomy, ventriculoperitoneal or ventriculoatrial shunting and syringoperitoneal shunting. The choice of procedure is based on the suspected cause of the syringomyelia and the anatomic data obtained by MR imaging.

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Surgical Therapy for Medically Intractable Epilepsy in Children

The renewal of interest in the surgical treatment of medically intractable epilepsy is well illustrated by the occurence of two international conferences devoted to the subject in the past six months, after more than a dozen years without one. This renewed interest extends to the use of surgical approaches in children with difficult seizure problems. Cortical resection is the surgical approach most likely to completely control seizures. The indications for cortical resection in children in their early teens (and perhaps even younger) are the same as for adults: medical intractability, the presence of a focus of seizure onset and evidence that the focus is not in a brain area essential for motor, speech or memory function. Most of these patients will have temporal lobe epileptic foci. Medical intractability means a persistence of seizures after trials of the major antiepileptic drugs at therapeutic serum concentrations: phenytoin and carbamazepine alone and together for complex partial seizures of temporal lobe origin. Most patients who achieve seizure control on antiepileptic drug therapy do so within six months of reaching therapeutic drug concentrations. Children in their early teens with partial complex temporal lobe seizures seldom outgrow them; waiting for this to occur, therefore, is not a reason to defer surgical treatment. The more satisfactory rehabilitation that follows seizure control in the teens rather than the 20s is a reason to consider earlier surgical intervention.

Papers given at recent conferences indicated that no one diagnostic approach is suitable to identify a focus in all patients. In one subset of candidates who are particularly likely to have their seizures controlled by a surgical resection, the focus can be identified by noninvasive means without the use of depth electrodes or other techniques of ongoing direct brain recording. The exact noninvasive criteria used by varous centers differ but often include localized interictal epilepticform abnormalities on scalp electroencephalography (EEG), evidence of fast motor responses and a lack of psychopathology on neuropsychological testing or measures of focal functional deficit, especially evidence of localized glucose hypometabolism on positron emission tomography. On the other hand, ongoing direct brain recording techniques have been of value in other patients who do not meet these noninvasive criteria due to bilateral, especially bitemporal, epileptiform abnormalities. In a large proportion of those patients, direct brain recording, coupled with intensive video and EEG monitoring, has shown that most or all major, socially disabling seizures arise from one temporal lobe. Surgical resection of that temporal lobe has a reasonable chance of controling major seizures. A wide variety of ongoing direct brain recording techniques are currently in use, including sterotaxically implanted depth electrodes, subdural strips and tubes and subdural or epidural plates of electrodues. The advantages of each approach are still being determined.

The hemisphere containing the epileptic focus for language and memory is usually determined preoperatively by intracarotid perfusion of amobarbital (Wada test), a procedure that can be used in children as young as 6 years. If the focus is in the dominant hemisphere, the areas essential for language are localized by electrical stimulation mapping and these areas spared in the resection. The intraoperative use of this approach, however, requires the use of local anesthesia that children in the early teens, and perhaps younger, will tolerate. The use of epidural or subdural plates of electrodes provides an alternative technique to obtain the same localization information in children who cannot tolerate a procedure under local anesthesia. Resections can also be carried out in a temporal lobe essential for memory, but this requires sparing both hippocampus and lateral temporal memory areas as identified by electrical stimulation mapping. With the use of these techniques, the risk to language and memory is sufficiently low that having the epileptic focus in the dominant hemisphere is not a reason for deferring resection.

The decision to undertake a surgical resection should be made based on the impact to a child of the control of seizures alone. Behavioral problems do not reliably improve after an operation for seizure control, and this goal is not by itself an indication for surgical therapy for seizures.

Surgical therapy may also be of value in several special situations. In very young children, surgical therapy is usually reserved for intractable seizures with a clear focal onset; a substantial number of these children will have the distinctive pathologic changes of Rasmussen's encephalitis. Children with the infantile hemiplegia syndrome have a high probability of seizure control after hemispherectomy. Recent modifications in the technique of this operation seem to have reduced the long-term complication of bleeding into the resection site and the subsequent development of a communicating hydrocephalus. The value of sectioning the corpus callosum in the treatment of seizures is still being debated. There is a developing consensus, however, that it may have some value in patients with frequent major motor convulsive (grand mal) seizures without a focus and in frequent drop seizures where the patient is likely to sustain injury.

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Chemotherapy in Conjunction With Blood-Brain Barrier Modification in Patients With Cerebral Metastasis

One of the major phenomena responsible for the failure of chemotherapy in the treatment of central nervous system (CNS) tumors may be the unique anatomic aspect of the blood-brain barrier. This structural barrier, composed of tight junctions between CNS capillary endothelial cells, serves primarily a protective regulatory function constraining diffusion across capillaries in relation to lipid solubility and molecular weight. Whereas it was formerly suggested that there was no effective barrier to drug delivery in CNS tumors, more recent studies indicate that considerable variations in barrier integrity exist between tumors, within the same tumor and particularly at the actively proliferating edge of a tumor. The clinical expression of the barrier is exemplified by the reports of increasing size of brain metastases when other extraneural parenchmal sites of tumor invasion regressed due to systemic chemotherapy.

The extent to which the blood-brain barrier limits drug delivery to CNS tumors remains an area of controversy and extensive investigation. Expansion of our studies in animals provided the basis for clinical trials, and we are presently evaluating clinical efficacy in a Phase II trial using combination chemotherapy (methotrexate sodium given intra-arterially and leucovorin calcium rescue by mouth, cyclosphosphamide given intravenously and procarbazine given orally) in patients with glioblastoma, CNS metastasis and CNS lymphoma. To date, 89 patients have received combination chemotherapy in conjunction with blood-brain barrier modification in 590 procedures.

In our small pilot series of seven patients with CNS metastasis (from breast, lung or testicle), three observations are of note. In one patient, a metastitic lesion was evident on enhanced computed tomographic (CT) scan only after osmotic barrier modification, supporting the existence of a completely intact blood-brain barrier in the tumor. Second, in another patient there was radiographic documentation of tumor regression in those areas of the brain infused while tumor progressed in portions of the brain distant from the areas of barrier opening. Third, the increased delivery of chemotherapeutic agents associated with barrier modification may be of benefit even in those patients who have undergone surgical and radiation therapy and systemic chemotherapy.

We have observed the following complications in our overall series of 89 patients: infarcts (3%), transient exacerbation of preexisting neurologic deficits—presumably due to an increase in brain water secondary to blood-brain barrier modification—(50%), seizures (15%) and readmission to hospital when patients have fever and granulocytopenia (33%). The significance of these studies relates directly to the grave prognosis associated with cerebral metastasis. Drug delivery is a major factor in treatment and reversible osmotic blood-brain barrier modification is likely to enhance the delivery of cytoreductive agents with minimal toxicity.

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Stereotactic Interstitial Irradiation (Brachytherapy) of Malignant Gliomas

Brachytherapy involves implanting radioactive sources directly into a tissue to deliver a calculated dose of radiation to a specific volume of that tissue. The technique has special appeal in neuro-oncology. The doses that have been delivered to the periphery of a brain tumor by brachytherapy are in the range of 3,000 to 12,000 rads compared with about 6,000 rads for standard teletherapy. The radiation dose delivered by combined brachytherapy and teletherapy may be substantial for the treatment of malignant gliomas.

Three factors have provided the impetus for an aggressive reevaluation of brachytherapy in managing malignant gliomas. The evolution of computed tomographic (CT) imaging technology has been combined with CT-scan-compatible sterotactic equipment and with improved computerized planning of radiation therapy. Current practice requires a confirmatory stereotactic biopsy of the lesion followed by placement of catheters into the tumor in locations selected on the basis of computer-generated isodose curves that precisely encompass the area on CT scan. The final array of the radioactive sources are afterloaded into the catheters. The sources are left in place until the calculated total dose has been delivered at a dose rate of 20 to 100 rads per hour. The dose rate depends on the specific activity of the isotope, the number of radioactive sources and their geometric distribution. The isotope ribbons and catheters are removed at the bedside on completing the radiotherapy plan.

The treated area undergoes radionecrosis and the fate of this damaged tissue is critical to the success, failure and complications of the therapy. If this technique is to be curative, the tumor under treatment must be localized and completely contained within the isodose curves that provide a dose sufficient to destroy the tumor. If these criteria are not met, then the treatment is palliative at best. In some patients, a delayed radionecrosis in the tumor volume can be progressively harmful by producing intractable cerebral edema. The experience of Gutin and Leibel with high-enery iodine 125 sources has resulted in a need for a craniotomy to remove a radionecrotic mass in about 30% of patients after implantation. Many of these patients, however, will have excellent long-term control of their disease, and the duration of survival achieved with recurrent malignant gliomas is superior to the best chemotherapeutic trials. The quality of prolonged life, however, has yet to be satisfactorily reported.

Many factors have to be studied before brachytherapy is recommended as standard therapy for malignant glioma. What role might the magnetic resonance imaging scan have in selecting focal versus diffuse gliomas? What is the best radiologic technique to define the "living" perimeter of the tumor? Should the treatment be restricted to recurrent disease or might it supplement teletherapy at some unknown ideal interval after completion of initial treatment and in relation to an unknown schedule of chemotherapy and radiosensitizers? What isotope is best? What is the ideal dose-rate and total dose of radiation to the tumor periphery? What is the ideal number of catheters to produce a homogeneous distribution of radiation? Is the frequency of symptomatic radionecrosis less with a particular technique of radiodosimetry? Are there anatomic sites of tumor or tumor geometries that are ideal for or that contraindictate brachytherapy?

The technology and equipment required to do brachytherapy are now commonplace. Until these questions are answered in authoritative studies, however, brachytherapy remains a therapy under review.

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Intrauterine Surgical Procedures and the Management of Hydrocephalic Fetuses

Before the early 1960s, experience with human fetal operations was nonexistent. Ten years later, refinements were being made with ultrasonography that led to unprecedented images of the fetal anatomy. With current technical advances, high-resolution, real-time ultrasonography can portray excellent detail of the entire fetus and, in particular, the developing nervous system. At 9 and 12 weeks of gestational age, the fetal skull and lateral ventricles, respectively, can be recognized. Although fetal hydrocephalus has become easy to identify during the third trimester, earlier detection of ventricular enlargement—that is, during the second trimester—continues to pose a difficult management problem.

Experience with animal models of fetal hydrocephalus seemd to indicate that in utero diversion of cerebrospinal fluid to the amniotic cavity was beneficial in reducing the adverse effects of hydocephalus, such as ependymal destruction, periventicular gliosis and loss of the cortical mantle. Several reports have now been published describing the placement of ventriculoamniotic shunts into hydroephalic human fetuses. Although ventricular decompression was achieved in most of the reported cases, technical problems such as shunt migration and malfunction were not insignificant. Perhaps the most important observation in this group was the associated anatomic defects involving the central nervous system (CNS). Highly skilled ultrasonographers using the most advanced equipment may fail to recognize these associated defects. Thus, false expectations regarding survival and future outlook based on sonographic data may lead to inappropriate in utero invervention.

Tantamount to the recognition of these associated anomalies is understanding the natural history of fetal hydrocephalus. In a retrospective analysis of 24 cases with fetal ventriculomegaly followed to term, Glick and colleagues indentified 11 fetuses that had isolated ventricular enlargement without associated life-threatening anomalies. Of the 11 fetuses, 10 showed stable ventricular size throughout gestation; only one fetus showed a progressive increase in the size of the ventricles. Three newborns required a shunt due to increased intracranial pressure. Additional CNS malformations were recognized in three cases soon after birth, however, which again points out the limitations of fetal ultrasonography. In addition, 80% of those infants requiring ventricular shunt procedures developed normally, emphasizing the unlikeliness of improving outcome with an intrauterine ventriculoamniotic shunt.

Most neurosurgeons have now placed a moratorium on the in utero treatment of fetal hydrocephalus. The high incidence of concomitant congenital anomalies associated with fetal ventriculomegaly, a better understanding of the natural history of this entity and a lack of adequate time for follow-up on those infants who undergo intrauterine shunt insertion justifies this prenatal policy of nonintervention. A fetus in the midtrimester that is normal by routine screening methods but showing progressive ventricular enlargement and no other recognizable defects repesents a challenging therapeutic dilemma. If pulmonary maturity can be verified or induced with steroids, delivery should be carried out and a shunt placed. If the viability of the fetus is questionable, however, a conservative approach seems indicated until maturity develops and warrants preterm delivery.

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AIDS and the Nervous System

Epidemiologic studies have shown that fully 39% of patients with the acquired immunodeficiency syndrome (AIDS) have significant neurologic complaints, and neurologic symptoms led to the initial diagnosis in 10% of all patients with AIDS. These patients most frequently present with progressive dementia, although seizures and focal neurologic deficits are common. Computed tomographic (CT) brain scans are normal in 41% of these patients and show diffuse cerebral atrophy in 38% and space-occupying lesions in 22%. Those patients with atrophy on CT scans appear to be at a higher risk of neurologic progression than those with normal CT scans. Recent studies indicate that magnetic resonance (MR) imaging is much more sensitive than CT for showing intracranial pathology in a patient with eurological symptoms, and thus MR imaging is now the neuroimaging procedure of choice in the screening of these patients.

The most common neurologic symdrome in a patient with AIDS is subacute encephalitis; this progressive, invariably fatal, dementing illness probably results from primary infection of the brain with human T-cell lymphotropic virus type III, the virus presumed to cause AIDS. The other most frequent neuropathologic processes included cryptococcal meningitis, *Toxoplasma gondii* encephalitis or abscess or both and primary central nervous system (CNS) lymphoma. There have been several reports of multiple coexisting intracranial pathologic conditions developing in AIDS patients.

Current recommendations for the evaluation of a patient with AIDS who has CNS symptoms include initial screening with MR imaging. If a space-occupying lesion is identified and the patient is neurologically stable, an empiric trial of antitoxoplasma therapy is instituted. If the patient is neurologically unstable, harboring a large mass lesion with risk of herniation or fails to respond to a three-week trial for presumed toxoplasmosis, biopsy is indicated. As several intracranial pathologic conditions may exist, repeat biopsy of lesions that progress despite specific therapy may be indicated to identify other treatable processes. In those patients without lesions on MR imaging, lumbar puncture should be done and treatment initiated on the basis of the cerebrospinal fluid findings. Those patients with normal neuroradiologic and cerebrospinal fluid findings warrant close clinical follow-up and repeat studies at regular intervals or at the time of neurologic progression.

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Ultrasonographic Evaluation of Carotid Artery Disease

Noninvasive screening tests of the carotid bifurcation, which aid in selecting patients for carotid arteriography, help avoid the morbidity and cost of that procedure and provide for safe serial examination of carotid disease. The two most widely accepted, increasingly available and reasonably accurate tests are duplex ultrasonography or scanning and digital intravenous angiography. Duplex scanning combines a B-mode, range-gated, short pulse ultrasound beam producing a high-resolution, real-time image of the vessel with a spectrum analysis display of the blood flow frequencies and amplitudes at that locus.

Both digital intravenous angiography and duplex scanning are highly sensitive for detecting stenotic lesions of 50% or more, with neither test being clearly superior. Digital subtraction angiography tends to underestimate disease severity in 72% of cases, whereas duplex scanning tends to overestimate 64% of the time. Duplex scanning is excellent for visualizing the "soft plaque," but its specificity for ruling out any degree of disease is only 20%. Spectral analysis improves considerably the accuracy of the B-mode image by detecting minimal and calcium-covered lesions usually overlooked by the latter. In several studies of stenosis alone, duplex scan sensitivity ranged from 90% to 95%, specificity 87% to 96% and accuracy 86% to 95%. Results of ultrasound studies agreed with those of a conventional angiogram absolutely in 71%, well in 20% and poorly in 9%.

Besides requiring a skilled technician, duplex scanning presents other disadvantages such as difficulty in differentiating a tight stenosis from a total occlusion and in identifying ulcerations.

Indications for duplex ultrasonography include an asymptomatic bruit, syncopal episodes, vague neurologic symptoms that might represent stroke, serial assessment of carotid lesions, detecting recurrent stenosis in patients following carotid endarterectomy and screening of patients scheduled for hypotensive anesthesia. It has recently been used intraoperatively to detect flaws in carotid reconstruction. Patients with typical carotid disease symptoms of amaurosis fugax, hemispheric stroke or transient attacks are better studied by conventional biplane arteriography because the likelihood of surgical or aggressive medical treatment is high. Ultrasonography does not delineate the aortic arch vessels, the cervical carotids cephalad to the mandible or the intracranial vessels.

The use of noninvasive testing such as duplex scanning results in a higher yield at cerebral angiography in patients with severe carotid occlusive disease. Nevertheless, the conventional biplane arteriogram at present is still the gold standard for analyzing carotid artery disease, and the final decision to proceed with it must still be based on clinical judgment.

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Cranial Neuropathies

Microvascular impingement on certain cranial nerves as they traverse the subarachnoid space of the posterior cranial fossa appears to be related (perhaps even causally) to the development of specific sensorimotor syndromes. Cross-compression of these neural structures may produce a focus of hyperexcitability that is manifest in a clinical syndrome relevant to the area mediated by the particular cranial nerve. In the case of the fifth or trigeminal nerve, the syndrome produced is trigeminal neuralgia. In this disorder, patients typically experience unilateral, lancinating, electric shock-like facial pain. If the seventh (facial) nerve is involved, unilateral, paroxysmal facial twitching, which often begins in the region of the orbicularis oculi, termed hemifacial spasm, is the result. Vascular distortion of the glassopharyngeal (ninth) and vagus (tenth) nerves can lead to glassopharyngeal neuralgia. In this syndrome, pain occurs in the pharyngeal region that resembles that of trigeminal neuralgia in its temporal pattern and lancinating quality. Other syndromes purported to result from microvascular compression of the acoustic (eighth) or the spinal accessory (eleventh) nerves have been described but have not yet been as widely accepted.

Although most cases of trigeminal neuralgia respond, at least intially, to carbamazepine therapy, hemifacial spasm and glossopharyngeal neuralgia respond poorly to this and other medical therapy. If the diagnosis can be made and the particular syndrome is refractory to medical management, these patients are candidates for microsurgical decompression of the involved cranial nerve. This is done under general anesthesia via a posterior fossa craniectomy. The cranial nerve is visualized with the aid of an operating microscope, the offending vessel is carefully moved from its point of contact with the nerve and a small piece of teflon felt is interposed between vessel and nerve.

Success with this surgical approach depends on the particular cranial nerve decompressed. In cases of trigeminal neuralgia, an initial success rate of up to 97% and a long-term rate of 80% can be anticipated. Both hemifacial spasm and glossopharyngeal neuralgia are eliminated in about 80% of patients after microvascular decompression of the respective cranial nerves. These procedures have been carried out now for more than a decade and long-term follow-up indicates these impressive results have persisted.

Clinical and laboratory research efforts have neither yielded the mechanism of these cranial neuropathies, nor have they precisely determined what role the microvascular cross-compression plays. Further questions remain as to why certain nerves seem prone to the development of a clinical syndrome, while others are minimally so. Future investigative efforts may clarify whether other disorders stem from vascular compression of neural structures in the posterior fossa. Nevertheless, microvascular decompression offers an important method of treatment in a growing number of cranial nerve syndromes.

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Magnetic Resonance Imaging

Over the past two years, in a dramatic technologic advancement, magnetic resonance (MR) imaging has assumed an important role in neurodiagnosis. Although computed tomographic (CT) scanning is still the better technique for assessing most acute cranial or spinal disorders involving hemorrhage or trauma, MR imaging has proved capable of visualizing a variety of central nervous system lesions that in some instances cannot be seen on CT. Remarkable images of such lesions, including multiple brain lesions seen at times in multiple sclerosis, the acquired immunodeficiency syndrome, brain abscesses and metastatic tumors, have been obtained.

Because MR imaging is extremely sensitive to changes in the brain water content, lesions associated with brain edema—the gliomas, meningiomas and intracerebral hematomas, among others—are readily visualized. Bone does not show up well on MR images, and so this technique is particularly valuable in assessing posterior fossa lesions, such as brain-stem gliomas, acoustic nerve sheath tumors and infarction—conditions for which CT is at a disadvantage because of bone artifact or because many of these lesions are nearly isodense with brain on CT. Conversely, MR imaging is not as consistently useful as CT scanning in evaluating bone abnormalities unless the bone lesion is caused by tumor involvement.

MR imaging has rapidly been accepted as the superior diagnostic test for many spinal cord and spinal canal abnormalities. Cord or dural sac compression is seen readily on MR images. Nerve root compression by a herniated intervertebral disc, though, may still be best evaluated by CT or myelography. Spinal cord tumors and syrinxes can be defined well on MR images, whereas they may not be seen at all on other studies. With conventional or CT myelography, their presence often can only be inferred by cord widening. Conventional myelography soon may be used only rarely, in view of the minute detail displayed by MR imaging and the improvement in CT spine images that has been obtained.

Because MR imaging is generally more sensitive than CT in detailing brain and spinal cord lesions, it is in many cases, wherever available, the procedure of choice for an initial dignostic study. The exceptions are patients with acute trauma, stroke or suspected intracranial hemorrhage, in which cases CT scanning patients who may have metallic implants. The cost of CT scans and MR imaging of the spine and brain is comparable. Recognizing the value of MR imaging, the State of California's Medicaid program (MediCal) now provides reimbursement for MR imaging done to evaluate brain and spinal cord pathology. The safety, efficacy and sensitivity of MR imaging have established its position as a critical diagnostic tool for neurologic disease.

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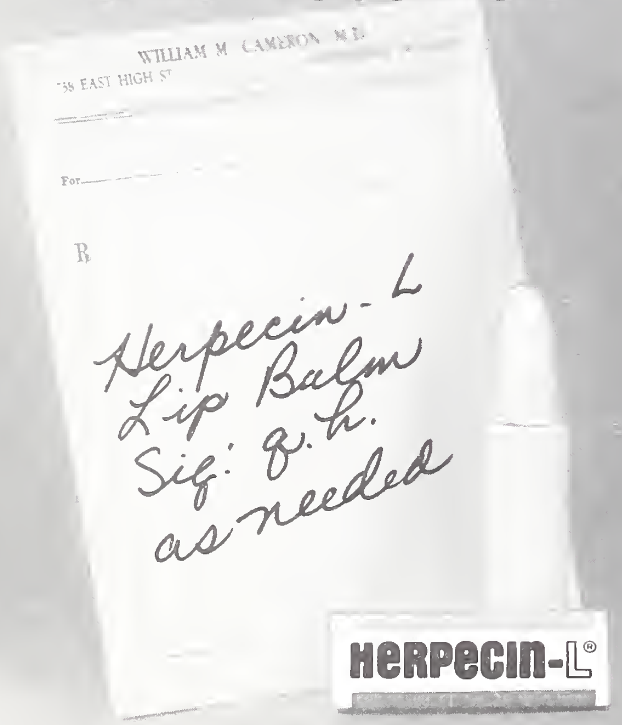

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M.D. HMO: Background

CSMS-IPA, INC.

In 1985, CSMS leaders identified the increasing proliferation of alternative fiscal intermediaries (HMOs) in the health care market as a major issue for Connecticut physicians. Of particular concern was the impending entry into the market of large outside corporations seeking to profit from the fragmentation of the system at the expense of Connecticut providers and patients, thus diluting cost savings to be realized from such alternative systems. Of greatest concern, however, was the erosion of the physician-patient relationship, and the intrusion of nonmedical factors into medical decision-making by physicians and their patients.

The concept of a statewide physician-owned IPA-HMO was discussed by the Society's Council in October of 1985, and a feasibility study was authorized by the House of Delegates in November. The Garvey Group of Norwalk was hired to carry out the study, which was presented to the House of Delegates at its May, 1986 meeting. The study identified that a "window of opportunity" existed for a unified statewide HMO, given expeditious action by a majority of practicing CSMS members in the state, and identified a number of advantages to be realized for physicians, their patients, and the employers of the patients, while assuring the patient's freedom of choice and the medical quality of the health care provided. After the presentation of alternative plans, the CSMS House of Delegates voted without dissent to implement the recommended proposal, and set a number of standards calling for a single statewide IPA and HMO, physician ownership, and open access for patients to the statewide panel of physicians.

Following a response by some thirty HMO development firms to the CSMS RFP, and presentations by several applicant firms, the Society selected LeBoeuf Consultants, Inc. of Boston to develop the statewide HMO with a goal of operational status by January, 1987. Meanwhile CSMS undertook to organize the CSMS IPA, Inc. in June and early July, 1986, resulting in the recruitment of nearly 2500 physician enrollees from every region and specialty during that period, a clear majority of CSMS active practitioners. Active recruitment resumed in September to increase IPA enrollment to beyond the 3000 mark in October prior to the anticipated HMO stock offering. Each IPA enrollee has contributed at least $500 to provide funding for HMO development, and their applications are now being screened by the CSMS-IPA Credentialing Committee.

Through this development of Connecticut's first statewide IPA-HMO, these physicians of CSMS reaffirm their commitment to providing optimal levels of quality health care to Connecticut residents in the most cost-effective delivery system possible. To accomplish this, these physicians will seek no subsidies, but will put themselves at risk financially and professionally, asking only for the opportunity to compete vigorously for a portion of this burgeoning and highly competitive market.

The common goal of these physicians is to establish a statewide HMO that will better serve the health and health-financing needs of the people of our state—their patients—with standard-setting quality and cost-effectiveness.

This background article is taken from the state licensure application of M.D. HMO, the new CSMS-sponsored statewide IPA-HMO.

The Steering Committee is chaired by William A. Whalen, M.D., of Willimantic.

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The Integrated Approach to the Management of Pain

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Introduction

We have come a long way in our social and professional attitudes toward the management of pain that have changed and developed during the last half century. A prior consensus statement, published in 1979, stressed the "caring" as well as the "curing" role in the management of pain associated with terminal disease and called for a more humanitarian approach. Since the time of that statement, further progress has been made in understanding and assessing the multidimensional character of pain, advancing the state of pharmacological techniques, and developing a variety of nonpharmacological approaches to the treatment of pain. In addition, recent years have witnessed the advent and growth of multidisciplinary pain clinics employing a range of methods and styles for the treatment of pain. While no single model commands universal acceptance, this new commitment to utilizing multiple modes of treatment and employing the skills of a multidisciplinary team of health professionals has come to be known as the "integrated approach to the management of pain."

Despite these recent scientific advances in the understanding and treatment of pain, it is important to recognize that there is no "magic bullet" or universally accepted treatment for the relief of pain and suffering. Contemporary science and clinical practice cannot assure the full relief of all pain. The data indicate that there remains a proportion of patients whose pain presents difficult, and so far unsolved, problems for successful management.

Yet over and above these limitations posed by current knowledge and technology, many informed observers, supported by some scientific data, perceive continuing deficiencies in the clinical management of pain. Concerns are focused on reported undermedication of individuals with acute pain and chronic pain associated with malignant diseases as well as reported overmedication of people with chronic pain not associated with malignant disease.

There is reason for concern that the education and training of many health care professionals, for example, in schools of medicine, nursing, dentistry, and physical therapy, do not place adequate emphasis on contemporary methods of pain assessment and management. Furthermore, communications among physicians, dentists, nurses, other health care professionals, and patients regarding pain relief in clinical settings of both inpatient and outpatient types are less than adequate. These perceived deficiencies help to explain the attractiveness of collaborative approaches to pain management that stress joint efforts and enhanced communication among health care professionals. The multidimensional character of pain, the difficulty of assessment, and the multiplicity of possible interventions suggest the complexity of the task and reinforce the arguments favoring collaboration and shared responsibility among health care professionals in the management of pain. There is also an inherent role for the individual with pain, and often the family, in determining the course of treatment and participating in the process of pain management. Well-established ethical and legal principles require that individuals in pain have a significant voice in treatment decisions. It is therefore important that they be informed sufficiently to understand, appreciate, and make intelligent decisions regarding the approach to pain management.

Estimation of the prevalence and incidence of pain as indicators of the magnitude of the problem addressed in this report is of great importance. Clearly, based on self-reports and clinical experience, a large number of persons experience pain. However, reliable and valid estimates cannot be extrapolated from the data presented at this conference. Much of the information presented is based on reports from pain clinics that comprise only a small and nonrepresentative sample of persons with pain. Yet epidemiological, economic, and biostatistical data delineating the magnitude of the problem of pain in this country—to individuals, communities, and health care facilities—are fragmented and inadequate.

The term "integration" within the context of this consensus panel is used to describe an approach to the most effective use of pharmacological and nonpharmacological agents in the management of pain. In an effort to resolve some of the questions surrounding the integration of ap-

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From the Office of Medical Applications of Research, National Institute of Health, Bethesda, Md.

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proaches to pain management, the Warren Grant Magnuson Clinical Center, the National Cancer Institute, the National Institute of Neurological and Communicative Disorders and Stroke, the National Institute of Dental Research, and the Office of Medical Applications of Research, NIH, jointly sponsored a Consensus Development Conference on the Integrated Approach to the Management of Pain. The conference brought together biomedical investigators, physicians, dentists, psychologists, nurses, other health care professionals, and representatives of the public on May 19-21, 1986.

Following a day-and-a-half of presentation by health care experts and discussion by the audience, a consensus panel, drawn from the health care and lay communities, considered the evidence and data presented and agreed on responses to the following questions:

- How should pain be assessed?
- How should pharmacological agents be used in an integrated approach to pain management?
- How should nonpharmacological interventions be used in an integrated approach to pain management?
- What is the role of the nurse in the integrated approach to pain management?
- What are the directions for future research in pain management?

1. HOW SHOULD PAIN BE ASSESSED?

Pain is a symptom that arises in response to a noxious stimulus or tissue injury. In some instances, pain may persist after the tissue damage has healed or in the absence of evident tissue damage. Clinicians have found it useful to classify pain into three major categories based on etiology: pain following acute injury, disease, or some types of surgery (acute pain); pain associated with cancer or other progressive disorders (chronic malignant pain); or pain in persons whose tissue injury is nonprogressive or healed (chronic nonmalignant pain). An individual may have more than one type of pain.

Pain is a subjective experience that can be perceived directly only by the sufferer. It is a multidimensional phenomenon that can be described by pain location, intensity, temporal aspects, quality, impact, and meaning. Pain does not occur in isolation but in a specific human being in psychosocial, economic, and cultural contexts that influence the meaning, experience, and verbal and nonverbal expression of pain.

Verbal self-reporting and behavior measures have been developed to assess the characteristics of a person's pain. Self-reported pain assessments can range from a simple "yes" or "no" response to questions such as "Are you in pain?" to a complex battery of instruments that measure multiple factors. The McGill-Melzack Pain Questionnaire is a widely used tool that measures sensory, affective, and evaluative dimensions of pain. Other self-report tests consist of verbal descriptions that range from low to high amounts of the dimensions of pain to be measured and visual analog scales which may represent the entire continuum of a dimension of the pain experience. The degree of pain is reported by selecting a verbal descriptor or making a mark on the line to indicate the level of pain.

Pain behaviors can be measured by personal diaries kept by persons in pain to record such things as daily activities, self-reports of time of onset, pain severity, medication consumption, perceived effect of drugs, and reported response to pharmacological and nonpharmacological attempts of relief. In using direct observation, the clinician can document pain behaviors such as guarded movement, rubbing of painful areas, and sighing. Important to observe are the related practices of withdrawal and social isolation, drug abuse, overutilization of the health care system, and inordinate preoccupation with pain. Interpretation based on such observation warrants sensitivity to the patient's individuality, culture, and modes of pain expression.

The assessment of pain in children presents special problems and is a subject of current research interest. Clinical impressions suggest that children in pain may frequently be undertreated. The usual verbal testing techniques are not applicable for younger children, and measures of pain magnitude are imprecise in children at earlier stages of cognitive development. Since children of all ages can and do express their pain, innovations in assessment tools designed expressly for children must be developed. Assessment techniques that require magnitude estimates and cognition are also of limited applicability to special populations, for example, those who are cognitively impaired or faced with language, cultural, or educational barriers. More effective approaches to the assessment of pain in these persons with special needs deserve exploration.

The clinical assessment of the person with pain begins with diagnostic evaluation and clarification of the goals of therapy. These should be appropriate for the type of pain, its cause, and the characteristics of the individual affected. Also, when and how often pain assessments should be made varies. Expectations for improvement differ according to these factors. Repeated clinical measures of acute pain must be relatively short and should focus primarily on sensory description and comparative estimates of magnitude and intensity. At present, few valid and reliable acute pain measures exist. With chronic pain, assessment may be more productively focused on affective and evaluative aspects of the pain experience, as well as on its history and context. Many existing pain assessment measures are based on a chronic pain model. Recent research indicates that an attempt should be made to measure as many dimensions as feasible in all types of pain, although the relative importance of each dimension varies by pain type.

Acute Pain

The single most useful method for evaluating acute pain outside of the research environment is to ask the person how he or she feels. Assessment tools such as the visual analog scale may be adapted to the needs of the bedside and are easy to use. The McGill-Melzack Pain Questionnaire may be useful during the initial evaluation. However it may not be practical on an ongoing basis in the clinical management of the individual experiencing pain. Further testing to establish reliability and validity of several different types of pain-specific self-report and visual analog scales in the clinical setting is indicated.

Chronic Pain Associated With Malignant Disease

Wide variations exist among persons with chronic pain associated with malignant disease. At such times, self-reports, the visual analog scale, and the McGill-Melzack Pain Questionnaire are useful when the person's condition permits. At other times, some individuals are quite ill and may be motionless and silent and only the simplest descriptions of discomfort can be elicited from them. Care-givers should review evidence of change in appetite, activity, social interaction, sleep patterns, and the impact of pain on the quality of life.

Chronic Pain Not Associated With Malignant Disease

The primary objective when evaluating individuals with this kind of pain should include the level of function as it may not be possible to achieve complete relief of pain. Both self-report measures and direct observation of motor activity are useful. Measures of psychological function may be important in evaluating the individual's emotional state and coping mechanisms since depression can be an important factor in many persons. Outside the research environment practical measures such as an increase in physical activity or improvement in interpersonal relationships will reflect improvement.

Thus far, the evaluation of treatment effectiveness for pain has relied largely on clinical impressions of outcome. Clinical investigators are presently involved in the development of valid and reliable measures of appropriate short- and long-term outcome measures. This includes measures that are useful for longitudinal study of change over time, such as increase in physical activity, as well as measures of absolute endpoints. These include increased activities of daily living, improved patterns of socialization, and return to employment. Effective assessment has related economic effects as well since, in part, it determines eligibility for benefits.

2. HOW SHOULD PHARMACOLOGICAL AGENTS BE USED IN AN INTEGRATED APPROACH TO PAIN MANAGEMENT?

Individualization of Drug Therapy

There may be marked individual variation in intensity of effect for any dose of a drug. Variations in dose-response are due to variations in rates of drug absorption, metabolism, and excretion and to variations in cell or organ sensitivity to the drug, presence of disease, and variations in age and body size. Attention should be given to these variations in dose-response in individualizing drug choice and drug dosage for patients with pain.

Acute Pain

Surveys of hospitalized people with acute pain have found that many continue to have moderate or severe pain because their treatment has been with doses of narcotic analgesics that have been too low or given at too long an interval between doses. Reasons for low doses or doses given infrequently include incorrect assessment, insufficient knowledge of the pharmacology of the prescribed drug, and personal attitudes of the care-givers and patients alike about narcotic analgesics. Concern about the problems of addiction and respiratory depression is greater than the actual risk. Approaches to addressing such problems include educating health care professionals about analgesic drugs and making them aware of how their attitudes may affect their use or nonuse of narcotic analgesics effectively. Public education with respect to these issues is also important.

One of the innovative ways that may provide effective individualized analgesia and comfort for these people has been the development of patient-controlled analgesia (PCA). This technique utilizes a device that permits intravenous self-administration of narcotic drugs within limits of dose and frequency established by the physician.

Chronic Malignant Pain

There are many parallels in the inadequate treatment of cancer pain with the inadequate treatment of acute pain. Surveys of people with metastatic cancer have revealed that the majority have moderate or severe pain. Research has shown that narcotic analgesics given on a scheduled basis in adequate doses is an improvement over the former p.r.n. (pro re nata or as occasion arises, according to circumstances, or as is necessary) method of physician-ordered narcotic use and nurse- or pharmacist-interpreted administration of drugs to address these pain problems.

An additional issue of concern in this patient population is the development of tolerance. There is an indication that when dosage requirement increases, the reason can be disease progression and not always increased tolerance. Physical dependence does occur but is not of clinical significance in advanced disease.

Some people with metastatic cancer cannot achieve pain control by systemic narcotics. In many situations, dose-limiting side effects are a problem. The addition of other drugs such as steroids or nonsteroidal anti-inflammatory drugs to the regimen may improve pain control without enhancing drug toxicity. In addition, other modalities of therapy such as nerve blocks, neurosurgical procedures, radiation therapy, chemotherapy, and other appropriate interventions, while not considered in detail at this conference, should not be ignored in the care of the individual with cancer pain. An innovative approach to the treatment of cancer pain has been the exploration of new routes or methods of narcotic administration. These include continuous subcutaneous infusion, epidural and intrathecal routes, mucous membrane or transdermal absorption, oral formulations with slow release and absorption, and PCA.

One should be aware that many individuals with pain due to cancer early in the course of their illness can achieve pain control with nonarcotic analgesics. For this class of drugs as for the narcotics, individualization of dose and of drug is essential.

Chronic Nonmalignant Pain

People with chronic pain of nonmalignant cause are a heterogeneous group with a variety of illnesses. They are treated with a wide variety of medications and other therapies, often with limited success. In an effort to alleviate the pain, drug dosage is often progressively raised to the point at which significant side effects appear. In addition to the established analgesics, tricyclic antidepressants have been tried in some of these conditions with variable results. They are most effective when clinical depression accompanies pain. Phenothiazines may have been used in treating nausea or anxiety accompanying pain, but they are not effective as analgesics or as potentiators of analgesics. Special care should be taken to avoid overtreatment of these individuals, particularly with drugs that have a real risk of side effects or addiction.

Children and Infants

There are special problems in providing adequate analgesia for infants and children. These special problems are due to deficiencies in assessing pain and to the lack of sufficient knowledge about factors influencing drug action in this population. Special attention should be given to solving these problems.

Quality Assurance

We recommend that examination of the adequacy of pain relief for persons in the hospital or receiving services from other health care institutions and agencies should be made a part of existing quality assurance programs.

3. HOW SHOULD NONPHARMACOLOGICAL INTERVENTIONS BE USED IN AN INTEGRATED APPROACH TO PAIN MANAGEMENT?

This past decade has witnessed a dramatic increase in laboratory and clinical research on nonpharmacological approaches to pain management. Experienced clinicians report some success with a variety of nonpharmacological modalities, including acupuncture, biofeedback, transcutaneous electrical nerve stimulation (TENS), hypnosis, physical therapy, and behavioral approaches such as coping strategies, desensitization, modeling, operant conditioning, and relaxation. Diagnostic and therapeutic nerve blocks of many parts of the body may be useful in pain management and as predictors of the effect of neurosurgical intervention. Acupuncture and TENS are most commonly used for chronic musculoskeletal disorders. Biofeedback is often used for the treatment of headaches and painful vascular conditions. Investigators agree that now is an appropriate time to evaluate the effectiveness of each of these modalities with specific patient populations through the use of controlled studies.

Behavioral therapies are used for some individuals with chronic pain. Practitioners believe that such therapies they are indicated when excessive pain behavior is inconsistent with other clinical findings. They are also used when there is a progressive decline in activity, evidence of abuse in pain medications, or an inordinate dependence on spouse or family members.

Biofeedback involves giving individuals information about physiologic responses and ways to exercise voluntary control over these responses. It is useful in muscle tension headaches and migraine headaches. A variety of relaxation techniques can be used in reducing pain associated with stress or anxiety.

With regard to the nonpharmacological approaches to pain, there must be a willingness on the part of the patient to participate with the clinician in the decision about which modality to use. In addition, it is important that the family members be educated about the proposed modality and their role in its application. Persons uncomfortable with or unwilling to take potent drugs for the relief of pain may be more willing to consider nonpharmacological approaches.

The various modalities, singly or in combination, can be utilized in the management of acute or chronic pain. Some persons may require a simultaneous or sequential combination of multimodal approaches incorporating pharmacological and nonpharmacological approaches in pain management.

4. WHAT IS THE ROLE OF THE NURSE IN THE INTEGRATED APPROACH TO PAIN MANAGEMENT?

While the consensus panel was asked to investigate particularly the role of the nurse within this framework, it recognized and supports the significant contributions made by all members of the health care team to the management of the person with pain. The expertise of the members of various specialties of the medical profession is critical to the management of pain.

However, the nurse may be the first health care provider to encounter the person experiencing pain as well as to identify the problem of uncontrolled pain. Thus, many opportunities exist for nurses to enhance the effectiveness of care delivery to individuals with pain. The nurse can be the key link in facilitating communication between the individual and the family and other members of the health care team. In so doing, nurses, along with other health care professionals, can make a significant contribution in facilitating effective patient participation in the decision-making process.

The role of the nurse in the assessment and management of pain varies according to the type of patient population being served, the setting in which care is delivered, as well as the educational and professional experience of the individual nurse. In acute care settings, the nurse occupies a central position in assessing the individual with pain, in administering physician-selected therapeutic modalities, and in monitoring the condition of the person in pain.

For those individuals experiencing chronic pain who are being discharged from hospitals or other institutions, nurses are in a pivotal position to assess the congruence between the person's condition, need for care, and the community health, public health, or home health resources available for the management of the individual in the noninstitutional setting.

For individuals managed at home, the nurse is frequently the professional who provides care, maintains ongoing communication with the individual and family, monitors the situation, and serves as the link with other care providers.

The role of the generalist nurse should not be underestimated. Nurses at this level have the most consistent interaction with the individual experiencing pain. Examples of the types of interventions that should be provided by the generalist nurse include:

- Preoperative patient education to lessen postoperative pain.
- Nursing care plans that reflect individual medication schedules based on individual preference and activity schedules.
- Implementation of nonpharmacological methods during acutely painful events such as childbirth, burn wound debridement, and diagnostic tests.

The nurse who specializes in the assessment and management of persons with pain may serve as part of an interdisciplinary team or may be individually identified as a resource within a particular setting. The nurse who specializes at this level must also possess increasingly sophisticated skills in the areas of pain assessment, pharmacology, choices of route and timing of drug administration, and participation in nonpharmacological interventions.

Whether or not the nurse practices as a member of an interdisciplinary team, the nurse may be identified as the coordinator of patient care. In this role, the nurse must be able to communicate effectively not only with the person in pain but also with the entire family and health care team.

The role of the nurse with advanced preparation should include:

- Clinical management responsibilities such as titration of analgesics within a protocol according to the patient's level of analgesia, assessment, and participation in the use of both pharmacological and nonpharmacological modalities.
- Provision of consultation and educational services to other members of the nursing staff, other providers, and community groups.
- Active participation in research.

To fulfill these roles effectively, nursing curricula must include pain management content. Nurses practicing in nursing service, nursing education, and nursing research settings should be provided with fellowships for further study of pain management.

5. WHAT ARE THE DIRECTIONS FOR FUTURE RESEARCH IN PAIN MANAGEMENT?

Future research should be directed to:

- Identify the factors that facilitate or hinder the dissemination and implementation of up-to-date information in clinical practice in the treatment of pain.
- Determine the appropriateness of using existing research measures in clinical settings and to evaluate their validity as adjuncts to clinical judgments in pain assessment. Investigators should consider the special issues related to children in pain that have received less attention in the past.
- Identify the specific factors associated with outcome within treatment modalities.
- Assess more fully the potential value of each of the nonpharmacological approaches to pain in acute and chronic pain states through controlled studies in specific populations.
- Discover and develop more effective analgesic drugs with larger margins of safety. Precise knowledge about the pharmacology of known drugs is important, but the development of medicine with new intrinsic actions and new drug molecules is needed. The basic research needed to improve the pharmacological therapy of pain will have to be performed in humans and many species of animals and should utilize a wide variety of research disciplines and methodologies.
- Continue research on endorphins, enkephalins, and narcotic receptors that shows promise of producing better analgesic drugs. In addition, this research may contribute to a better understanding of the mechanisms of such nonpharmacological therapy as acupuncture and TENS.
- Develop and evaluate methods of drug delivery, including PCA, sustained release formulations, epidural administration, and transdermal absorption of narcotic drugs to improve pain management with presently available narcotic drugs.
- Conduct epidemiological studies of the incidence and prevalence of pain.
- Study the nature and meaning of pain in a variety of settings and within a broad range of populations as the basis of developing ethnoculturally and contextually appropriate assessment tools.

Throughout the conference, the theme emerged that no single treatment modality is appropriate for all or even for most individuals suffering from pain. The treatment, and the evaluation of that treatment, should vary with the constellation of factors surrounding that individual.

These considerations should guide future research.

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Opinions of the AMA Council On Ethical and Judicial Affairs

The AMA Council on Ethical and Judicial Affairs presented the following opinions to the AMA House of Delegates at its 1986 Annual Meeting for the information of the delegates.

REFERREL OF PATIENTS–DISCLOSURE OF LIMITATIONS. When a physician agrees to provide treatment, he thereby enters into a contractual relationship and assumes an ethical obligation to treat the patient to the best of his ability. PPO and HMO contracts generally restrict the participating physician's scope of referral to medical specialists, diagnostic laboratories, and hospitals that have contractual arrangements with the PPO or HMO. Some plans also restrict the circumstances under which referrals may be made to contracting medical specialists. If the PPO or HMO does not permit referral to a noncontracting medical specialist or to a diagnostic or treatment facility when the physician believes that the patient's condition requires such services, the physician should so inform the patient so that the patient may decide whether to accept the outside referral at his own expense or confine himself to services available within the PPO or HMO. In determining whether treatment or diagnosis requires referral to outside specialty services, the physician should be guided by standards of good medical practice.

ECONOMIC INCENTIVES AND LEVELS OF CARE. The primary obligation of the hospital medical staff is to safeguard the quality of care provided within the institution. The medical staff has the responsibility to perform essential functions on behalf of the hospital in accordance with licensing laws and accreditation requirements. Treatment or hospitalization that is willfully excessive or inadequate constitutes unethical practice. The organized medical staff has an obligation to avoid wasteful practices and unnecessary treatment that may cause the hospital needless expense. In a situation where the economic interests of the hospital are in conflict with patient welfare, patient welfare takes priority.

MEDICAL TESTIMONY. As a citizen and as a professional with special training and experience, the physician has an ethical obligation to assist in the administration of justice. If a patient who has a legal claim requests his physician's assistance, the physician should furnish medical evidence, with the patient's consent, in order to secure the patient's legal rights.

The medical witness must not become an advocate or a partisan in the legal proceeding. The medical witness should be adequately prepared and should testify honestly and truthfully. The attorney for the party who calls the physician as a witness should be informed of all favorable and unfavorable information developed by the physician's evaluation of the case. It is unethical for a physician to accept compensation that is contingent upon the outcome of litigation.

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MORBIDITY AND MORTALITY CONFERENCES:
UNIVERSITY OF CONNECTICUT HEALTH CENTER

Recurrent Vascular Collapse in an 83-Year-Old Man

HENRY SCHNEIDERMAN, M.D., JOHN BRITTIS, M.D. AND FRANK MESSINEO, M.D.

ABSTRACT – A case of cardiovascular collapse in an elderly man that responded temporarily to fluid resuscitation is described. The patient became resistant to therapy and death soon followed. Autopsy demonstrated the causative lesion: acute aortic dissection with secondary hemopericardium. The differential diagnosis and pathophysiology of vascular collapse are discussed in particular relation to the pathologic findings.

Series Editor's note: Morbidity and Mortality (M and M) Conferences differ in an important respect from Clinico-Pathologic Correlation Conferences (CPCs), by incorporating pathologic information, including autopsy if available, in the data base. The discussions utilize the findings to gain further insight on diagnosis, management, and pathogenesis. The issue of arriving at the diagnosis is not a central concern as it is in CPCs.

The following represents an edited transcription of an M and M Conference held at the University of Connecticut Health Center, Farmington, CT, in 1986.

John Brittis, M.D.: An 83-year-old man with no known past medical history was admitted to hospital after successful cardiopulmonary resuscitation (CPR) in the field. He had been found in his automobile, unresponsive, without a blood pressure or pulse. Paramedics began CPR and placed an esophageal obturator airway. Endotracheal intubation was about to be performed when the patient awoke. At this time, the pulse was 140 beats per minute (BPM) and the systolic blood pressure was palpable at 60 torr (mm of Hg). In transit the patient was conscious and oriented. The cardiac monitor showed sinus tachycardia.

In the Emergency Room he denied symptoms, but acknowledged that he could not recall the incident. The systolic blood pressure was 80 torr by palpation, pulse 110 and regular. No paradoxical pulse was present. The temperature was 36.7°C rectally, the respiratory rate 22/min. The extremities were cool and clammy. The hands, feet, face and ears showed a purplish mottling, without frank cyanosis. Both lungs were clear, with good air movement, and no crackles (rales). Heart examination showed normal first and second heart sounds. No audible or palpable accentuation of the pulmonic component of the second heart sound (P_2) was present. There was no right ventricular lift, nor an abnormal apical impulse. There was a grade II/VI systolic ejection murmur at the left lower sternal border. There was no diastolic murmur, including that of aortic regurgitation. No ventricular gallop (S3), atrial gallop (S4) or pericardial rub was heard. Peripheral pulses including carotids, upper limb pulses and femorals were equal and symmetric. The estimated jugular venous pressure was 6 cm of water. The abdomen was soft, nondistended, and nontender, without mass or abnormal pulsations. Neurologic examination was nonfocal.

The hemoglobin was 13.6 gm/dl, the white count 10,000/cu mm. Blood chemistries were normal. No amylase level was obtained. Electrocardiogram (ECG) showed sinus tachycardia at 110 BPM, without changes suggestive of acute myocardial infarction or ischemia. On 10 liters of oxygen by Ventimask, the arterial blood pH was 7.36, the PO_2 89 torr, the PCO_2 27 torr. On 50% FiO_2, the pH was 7.32, the PO_2 149, PCO_2 27.

Margaret Szerejko, M.D. (Assistant Professor of Radiology): No previous radiograph was available for

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HENRY SCHNEIDERMAN, M.D., (Series Editor), Assistant Professor of Medicine and Pathology, Departments of Medicine and Pathology; JOHN BRITTIS, M.D., Chief Medical Resident, Department of Medicine; FRANK MESSINEO, M.D., Assistant Professor of Medicine (Cardiology), Department of Medicine; all of the University of Connecticut Health Center, Farmington, CT.

Grant Support: Dr. Schneiderman is a Teaching and Research Scholar of the American College of Physicians; Dr. Messineo is the recipient of a Clinical Investigator Award from the National Institutes of Health (HL-00911).

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comparison. A single supine portable chest x-ray was overpenetrated (Figure 1), but the lung fields appeared clear. There was no pulmonary vascular congestion or edema. The heart was borderline enlarged but had sharp outlines. There was no evidence of pericardial or pleural effusion. Prominence of the ascending aorta and arch, of ectatic origin, was consistent with the patient's age. The aortic knob showed scant calcification. Only 2 mm lay between this calcification in the intima or inner wall, and the outer margin of the aortic shadow. The descending aorta was straight. The superior vena cava and the azygos vein were not distended. The width of the mediastinum was normal for a supine film.

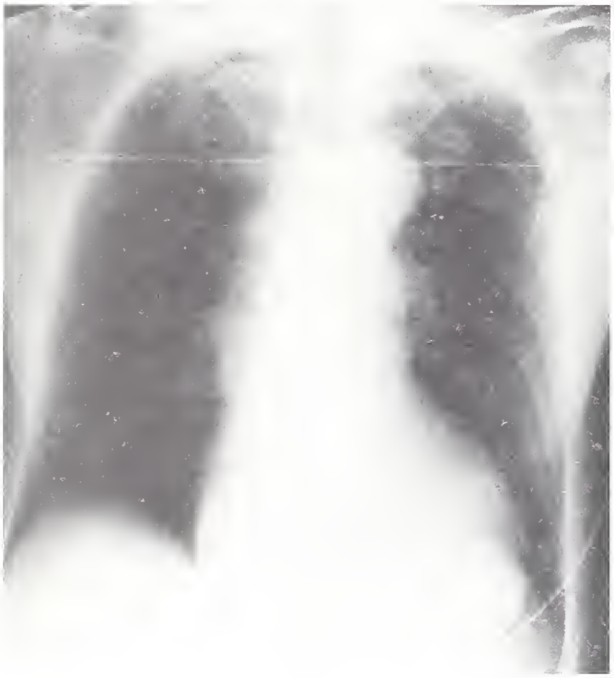

Figure 1

Portable chest radiograph shows no illuminating mediastinal, cardiac, pleuropulmonary or vascular features.

Dr. Brittis: Over the next two hours, 3 liters of normal saline solution were administered intravenously. The systolic blood pressure rose to 94 torr, and the pulse fell to 90. Urine output was 50 cc per hour. The patient remained alert and breathed spontaneously. Thereafter, the systolic blood pressure fell suddenly, and the jugular venous blood column rose sharply. The patient became confused, more mottled, and diaphoretic. Intravenous dopamine was started, but did not restore blood pressure or perfusion. The patient still had no pain. The heart rate increased and the patient became more obtunded. Cardiac arrest ensued. The patient was intubated, and CPR was restarted. Organized cardiac electrical activity resumed, but the QRS complexes were prolonged. The heart rate was 60, but no pulses were palpable. Echocardiography performed under adverse conditions during CPR showed no widening of the aortic root. A small pericardial effusion was seen. Spontaneous cardiac wall motion was not appreciated. The patient never regained consciousness, and died soon thereafter.

Henry Schneiderman, M.D.: At autopsy, 225 cc of clot and 150 cc of liquid blood distended the pericardial cavity, producing fatal cardiac tamponade. After evacuation of pericardial contents, hemorrhagic staining of the adventitia of the aorta was evident. The tunica media of the aorta had been split by hemorrhage. This hemorrhage within the media created a second, false aortic lumen (Figure

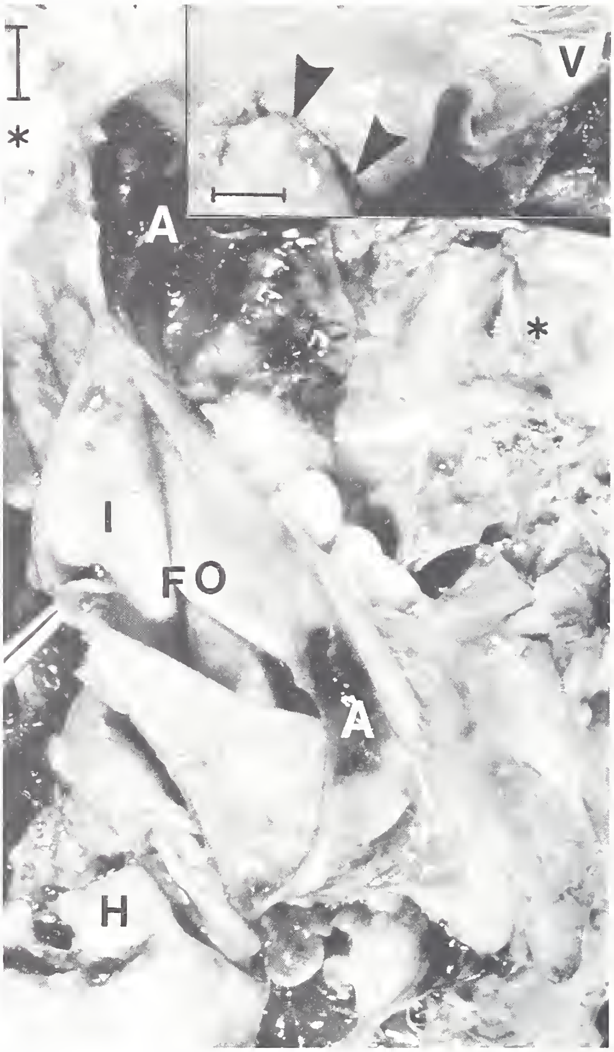

Figure 2

Autopsy specimen, after evacuation of pericardial contents, reveals blood-staining of aortic adventitia (A). An empty false aortic lumen (F) is created by separation of the outer (O) and inner (I) portions of the aortic tunica media. The intimal or endothelial surface (asterisks), which has been twisted by the prosector in upper part of photgraph, shows severe atherosclerosis. Note epicardial surface of heart (H). Bar is one cm long.

Inset shows rent in aortic intima (arrowheads), a few cm above aortic valve cusp (V).

2). The false lumen was completely surrounded by media, which consists of smooth muscle, elastic fibers and collagen, and forms the great bulk of the wall of the aorta. Three cm above the heart, and within the pericardial space, there was a defect in the adventitial surface. Liquid blood within the false lumen drained out at autopsy. The mediastinum was blood-stained.

A 3 cm *intimal* tear was present in the aorta just above the aortic valve and coronary ostia (Figure 2, inset). This tear produced a communication between the true lumen of the aorta, and the false lumen within its damaged media. Thus the blood tracked widely from the true aortic lumen through the aortic wall, creating a false lumen, and eventually exited through the adventitial defect mentioned above.

Histology confirmed that the outer part of the media was split from the inner by a wedge of fresh hemorrhage; red blood cells were seen on the outside of the aorta as well. The true lumen was lined by atheromatous intima. The false lumen had no endothelial or other lining. Rather, it consisted of a separation or cleft within the connective tissue. Collagen and elastin fibers, and smooth muscle were all decreased or absent across half the thickness of the aorta (Figure 3 and inset). Direct pressure injury from overlying atheroma produced spotty superficial elastic fiber fragmentation. None of these abnormalities were more severe where dissection occurred than elsewhere in the aorta.

Thus, the pathology constituted dissecting hematoma of the aorta. The lesion was not an aneurysm and should not be called dissecting aneurysm: the aorta was not aneurysmally dilated. Its outer dimension is normal in this condition, as the chest radiograph suggested. Although medial damage is common to both ordinary atherosclerotic aneurysm and dissecting hematoma, the two entities have little else in common. As to predisposing lesion, aging aortas can show the background changes in the media observed in this case. There is no reproducible difference between aortas in which dissecting hematoma occurs, and those in which it does not.[1,2,3,4] Thus, aortic dissection is an uncommon catastrophe surpervening on a common process of injury and repair.[2]

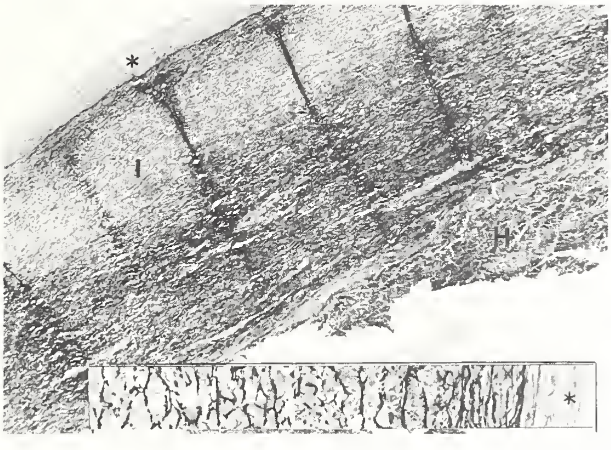

Figure 3

Histologic section demonstrates decreased elastic fibers, particularly in inner portion of media (I), producing paler staining. Intima (*) has only minimal atherosclerosis at this point. Fresh hemorrhage (H) encircles adventitia. (Elastic-trichrome stain, original magnification 40X).

Inset confirms loss of the great majority of elastic fibers (black lines), and of considerable smooth muscle (gray background), particularly in area farthest from intima (*). (Elastic-trichrome, original magnification 200X).

The background changes mentioned were present everywhere in the aorta, but the dissecting lesion was confined to the ascending aorta, so that it was a type II or proximal dissecting aortic hematoma. The vena cava was not compressed by the dissection. For this reason, the elevated central venous pressure was ascribed to tamponade alone.

Other findings included left circumflex coronary artery hemosiderin, reflecting prior hemorrhage into an atherosclerotic plaque. The myocardium was hypertrophic. There was no acute myocardial infarction anywhere in the left or right ventricles. The dissecting hematoma did not extend into the coronary circulation. Small-blood-vessel sclerosis was present in the heart, consistent with hypertension, the usual setting for dissecting hematoma. Substantial old cardiac microscarring, probably ischemic, was present. The lungs showed emphysema, slight pulmonary fibrosis, and a microscopic marrow embolus secondary to CPR. Nonspecific scars in the lungs suggested resolving pulmonary infarcts. However, no thrombi or emboli were seen grossly or on extensive microscopy. There was no evidence of old, *healed* dissecting hematoma of the aorta, a common finding in people who subsequently die of a final episode of dissection. A healed gastric ulcer was present. The kidneys showed nephrosclerosis, a soft sign of past hypertension.

In summary, this patient died of a large dissecting hematoma of the ascending aorta, associated with hypertensive damage to the media and severe atherosclerosis. The dissection ruptured into the pericardial sac, causing acute cardiac tamponade.

Frank Messineo, M.D.: This case provides a framework from which to approach the important differential diagnosis of sudden cardiovascular collapse and shock. Shock is a state wherein blood flow to vital organs is inadequate to maintain cellular function. During shock the cardiovascular system and its regulators (including the central nervous system), are unable, despite homeostatic mechanisms, to maintain systemic blood flow. Usually, patients in the shock state are hypotensive, but hypoperfusion can occur without hypotension.

Whatever the cause, the shock state is a catastrophe. It is important to ascertain the pathogenesis of shock because appropriate therapy differs and depends on the underlying mechanism. In most cases, therapy is much more effective when directed by a pathogenetic diagnosis.

A review of the components of the cardiovascular system will improve understanding of pathogenesis of the shock state. The cardiovascular system consists of a pump (the heart), with conduits (conductance, capacitance and resistance vessels); the size of these vessels is regulated both by impulses from the central nervous system and by local mediators of smooth muscle tone; and blood volume fills the system. Shock occurs when one or more of these components fails. For example:

1. Cardiogenic shock occurs when the heart fails as a pump.
2. Distributive shock occurs when the ability of the peripheral vascular system to regulate the distribution of blood volume fails, as in septic or in neurogenic shock.
3. Obstructive shock is present when resistance rises and flow falls in the vascular tree. This obstruction usually lies centrally, in the heart or great vessels, because flow there occurs in series through single conduits lacking collateral (parallel) circulation.
4. Hypovolumic (hypovolemic) shock occurs when the intravascular volume is critically decreased, for example, during hemorrhage.

Were there clues to the diagnosis in the history and physical examination? The history may help place this patient into one of the above categories. Sudden cardiovascular collapse and unconsciousness can be divided into cases where loss of consciousness precedes, or follows the development of the shock state.

A primary central nervous system event, such as sudden ischemia to the reticular activating system, or subarachnoid or intracerebral hemorrhage, can initiate reflexes leading to loss of consciousness. However, a patient with a primary central nervous system event causing loss of consciousness will almost always have focal deficits on neurologic examination after awakening. In the absence of localized findings, loss of consciousness usually represents a secondary central nervous system event due to low cardiac output. Reflexes whose afferents arise in the heart, pericardium, or vasculature can enhance vagal tone and produce transient cardiovascular collapse, i.e. vasovagal syncope. Therefore a persistent shock state without local neurological deficit after recovery of consciousness, incriminates the cardiovascular system as the cause of shock in this case.

The heart is the most likely culprit in cardiovascular collapse. Physical examination in this case provided useful information. The initial jugular venous pressure, an estimate of central venous pressure, was 6 cm of water. This normal finding helps exclude hypovolemic shock: in that entity, vasoconstriction is associated with low central venous pressure. The peripheral vasoconstriction, manifested by cool, clammy and mottled skin, suggested a low cardiac output state in this case. By contrast, in septic shock (or other distributive shocks), peripheral vascular dilation occurs early. The preserved central venous pressure and evidence of low cardiac output suggested obstructive shock, as may occur with pericardial tamponade, pulmonary embolus, or intracardiac thrombus or mass. Right atrial or superior vena caval obstruction could produce similar findings; and superior vena caval syndrome can result from dissecting hematoma. Pulmonary embolism is a cause of low cardiac output with elevated central venous pressure and right heart failure. Other possible etiologies include global myocardial dysfunction, and predominantly right-ventricular myocardial infarction.

Left ventricular myocardial infarction rarely causes elevated central venous pressure without pulmonary congestion. The absence of crackles (rales) on auscultation, and the lack of radiographic pulmonary congestion, argue against acute cardiogenic shock based on left ventricular dysfunction. The ECG did not show evidence of an acute myocardial infarction. Both transmural and subendocardial infarctions large enough to produce this patient's clinical state are usually evident on the ECG. Inferoposterior infarcts with concomitant right ventricular infarction, however, may lie hidden. Right-sided ECG leads, and echocardiography, may reveal them. The traditional masks of infarction, bundle branch blocks, were not present.

Sudden loss of consciousness could occur with cardiac arrhythmias. A persistent shock state lasting beyond the termination of the arrhythmia would need additional explanation. An arrhythmia producing loss of consciousness from low cerebral perfusion could also result in hypoperfusion of left ventricular myocardium. Such hypoperfusion could cause myocardial infarction, or a depression of myocardial contraction that might persist beyond restoration of sinus rhythm and coronary flow. The phenomenon of depressed or "stunned" myocardium can persist for days after relief of severe ischemia.[5] Again, the absence of pulmonary congestion makes such a sequence unlikely. Similarly, cardiovascular collapse caused by sudden aortic or mitral valve cusp rupture would be expected to produce both a characteristic murmur and pulmonary congestion, neither of which was present; the same logic excludes left atrial myxoma and mitral thrombosis.

What other diagnoses need to be considered with clear lungs, shock and preserved or elevated central venous pressure? A pulmonary embolism seems unlikely because the patient never experienced dyspnea even after regaining consciousness. The history, however, may be undependable, because a patient in a low-flow state is not a reliable observer. Therefore, the lack of dyspnea or chest pain may be misleading. When present, the pain of pulmonary embolism can be either pleuritic or, if massive, pressure-like. The absence of a palpable or augmented audible pulmonary component of the second heart sound, and of a right ventricular lift, argue against acute right ventricular pressure overload. Any pulmonary embolism responsible for cardiovascular collapse must be massive, obstructing more than half the cross-sectional area of the pulmonary vasculature. In such cases, right ventricular pressure overload is expected. In addition, the relative ease with which hypoxemia reversed on supplemental oxygen also suggests that no important intrapulmonary shunt was present.

Several other differential diagnoses deserve mention. Tricuspid valve obstruction from thrombus or myxoma can produce acute cardiogenic shock with high central venous pressure and no right ventricular lift. Pneumomediastinum and tension pneumothorax can produce sudden cardiovascular collapse, but history, examination and chest x-ray provide no evidence, and despite being found in his car, the patient had no signs of vehicular trauma to provide a setting for such conditions.

Intra-abdominal catastrophes can cause loss of consciousness and shock. In elderly patients, sudden depletion of intravascular volume is poorly tolerated because cardiovascular reflexes are blunted. Often, too, coexisting coronary artery disease or myocardial disease decreases cardiac reserve. A ruptured abdominal aortic aneurysm remains an important consideration. Hypotension and peripheral vasoconstriction would be present, but symptoms and signs referable to the back or abdomen would also be expected. The absence of a pulsatile abdominal mass, and an otherwise normal abdominal examination, decrease the likelihood of ruptured aneurysm. The normal examination makes ruptured abdominal viscus, acute pancreatitis, or bowel ischemia/infarction less likely. Finally, severe hemorrhage from peptic ulcer disease may occur with a negative physical examination of the abdomen. Many authors emphasize that an acute abdomen with shock and a negative abdominal examination suggests a hemorrhagic calamity.[6]

In this case the coexistence of three features points to acute cardiac tamponade from dissecting hematoma of the aorta: 1) loss of consciousness heralding a low-perfusion state, 2) an elevated central venous pressure, and 3) the absence of pulmonary hypertension. The absence of pain is unusual. Half of the patients with dissecting hematoma have pain as their only symptom, and 88% have pain as a part of the presenting history.[3] Like the history, examination of this patient lacked several common findings of dissection and its complications. There was no pericardial rub, no aortic insufficiency murmur, and no paradoxical pulse, and the peripheral pulses were all present and equal bilaterally. However, absence of a paradoxical pulse was not a useful negative because this sign is lost in tamponade in the presence of shock.[7] Investigations also did not show characteristic findings. The ECG was not consistent with a large pericardial effusion. The radiographic heart shadow was not enlarged; there was no left pleural effusion (hemothorax); and the mediastinal shadows were not abnormal.

What might have been done differently in managing this patient? Since retrograde aortic dissection into the pericardial sac requires emergent surgical therapy,[8] management must include temporizing measures to maintain organ perfusion while efforts to secure the diagnosis proceed quickly. The efficacy of acute non-surgical pericardial evacuation in this setting is unknown. Lowering the intrapericardial pressure could cause further bleeding, unless the false lumen were thrombosed. Did the use of an inotropic agent make the hematoma dissect further? It is possible, but the practical need to maintain organ perfusion made dopamine, an agent with both inotropic and vasoconstrictive properties, indispensable. Earlier echocardiography to assess myocardial function, to examine right ventricular size and function, or to demonstrate a pericardial effusion and assess its hemodynamic impact may have been warranted, but would not have altered outcome. Fluid in the pericardial space and elevated intrapericardial pressure are essential features for tamponade, and the rapid accumulation of as little as 200 cc may produce tamponade physiology. Other echocardiographic findings of cardiac tamponade include right ventricular compression and atrial obliteration during early diastole. Echocardiography may visualize a widened aorta and perhaps a false lumen, but the test is suboptimal for diagnosis of aortic dissecting hematoma. A flow-directed pulmonary artery catheter (Swan-Ganz catheter) would differentiate pulmonary hypertension from other causes of elevated right heart pressures, and thereby help exclude pulmonary embolism. It also could measure pressures characteristic of tamponade, but unfortunately, the outcome would not have been altered. Computed tomography may be useful to diagnose aortic dissection, but its sensitivity and specificity remain to be defined.

Dr. Szerejko: An aortogram would save time if immediate surgery for dissecting hematoma were contemplated. Most surgeons require aortography before operating. If there is a strong suspicion of dissecting hematoma, and the patient can tolerate the procedure, one should go straight to aortography to maximize the chance of survival.

Dr. Schneiderman: The pathology helps us understand why there was no aortic insufficiency. The exit point, that is the adventitial defect, was high up, and so was the pericardial reflection. The dissecting hematoma did not go down to the aortic valve. Thus, blood was able to enter and fill the pericardial space without compromising the aortic valve.

In addition, the absence of a left pleural effusion is more helpful in excluding distal dissecting hematoma than what this patient had, namely proximal dissecting hematoma.

Even if a surgeon worked immediately on this patient, the outcome would very likely have been death. The mortality is enormous even in operated patients with this condition when they are severely unstable perioperatively, as this patient would have been. Some surgeons have compared sewing the edges of dissecting hematomas to sewing butter. The technical problems are formidable.

Final Pathologic Diagnosis: Hypertensive cardiovascular disease, with dissecting hematoma of ascending aorta, type II, with intrapericardial rupture and cardiac tamponade.

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Fluid Resuscitation: Colloid Versus Crystalloid

RICHARD D'ANGIO, PHARM. D. AND ROCCO ORLANDO, III, M.D.

The controversy as to whether colloids offer a significant advantage over crystalloids has assumed increased importance in this era of cost containment since crystalloid replacement is much less costly than colloid therapy.[1-3] Advocates of colloids cite a decreased incidence of pulmonary edema,[4-9] shorter resuscitation time,[12] and more complete reversal of shock.[8,10-12] Proponents of crystalloid treatment believe patients can be effectively resuscitated with crytalloids alone with a decreased incidence of pulmonary edema and other complications.[2,3,12-18]

Theoretical basis for the use of colloids

Fluid flux between the vascular and interstitial space is dependent on hydrostatic and oncotic pressures as described by Starling.[19] The capillary hydrostatic pressure and the tissue oncotic pressure tend to cause the movement of fluid from the intravascular to the interstitial space. These forces are opposed by the tissue hydrostatic pressure and the oncotic pressure of the plasma which tend to maintain fluid in the vascular space. In order for the intravascular proteins to exert an oncotic pressure the capillary wall must be relatively impermeable to proteins. Proponents of colloid believe the capillary endothelium is relatively impermeable to plasma proteins and this situation is not adversely affected by disease states. Normally the net volume flow is slightly positive reflecting the constant movement of fluid into the interstitial space. Excess fluid in the interstitial space is returned to the vascular space by lymph flow and the equilibrium is thus maintained.[19]

Administration of large volumes of crystalloid dilutes oncotically active substances in the plasma.[4-6,8,9,11,20] This tends to favor the movement of fluid into the interstitial space. Because proponents of colloids believe that hypovolemic shock is due to a deficit in intravascular volume only, the movement of fluid into the interstitial space would not be beneficial. Increased extravascular water would enhance the formation resuscitation. The oncotic activity of plasma may be readily assessed by measuring colloid oncotic pressure (COP). A low COP has been shown to be associated with a poor therapeutic outcome although this may only be a marker of severity of disease.[6] Increasing COP with the use of colloids has not been demonstrated to improve survival.

Theoretical basis for the use of crystalloid

The original equation described by Starling included the incorrect assumption that the capillary membrane is totally impermeable to plasma proteins. Since then it has been shown that as the permeablity to plasma proteins is increased, the contribution of plasma oncotic pressure to the movement of fluid is decreased. Burns, trauma, sepsis as well as exposure to various toxins are known to increase the permeability of the capillary membrane.[21-23]

Although crystalloid resuscitation tends to decrease plasma oncotic pressure, a number of safety factors exist which prevent edema formation. Increased fluid entering the interstitial space decreases tissue oncotic pressure, increases tissue hydrostatic pressure, and increases lymph flow which tends to oppose the formation of edema.[19,23]

Also important is the fact that the gradient of capillary oncotic pressure to tissue oncotic pressure *does not change* in critical illness. Not only does fluid leak from the capillaries in these patients but colloids permeate the endothelial membrane as well.[22] Colloid administration is without long-term benefit as this treatment modality fails to establish a net increase in this gradient.

Patients fluid resuscitated with crystalloids require 2-4 times the volume compared to patients resuscitated with colloids. This is due to the redistribution of crystalloids throughout the extravascular space. This increased fluid volume is not necessarily deterimental because fluid depletion may exist in the interstitial as well as the intravascular space.[24]

Colliods versus crystalloids in the treatment of pulmonary edema

Although a number of studies[4-6,8,9,11] have suggested patients resuscitated with colloids developed less pulmo-

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nary edema, this tissue remains controversial. Criticism of these studies include: the use of preset fluid volumes,[4,11] overhydration of patients receiving crystalloids,[8] and use of a control group receiving crystalloids that may have been more severely injured.[4,5] Many of these studies also defined pulmonary edema by radiographic criteria only.[5,6,8,9] This was not shown in these studies to correlate with derangements in physiologic parameters.

The pulmonary interstitium is remarkably efficient at returning excess fluid to the intravascular space via the lymphatics. Administration of exogenous colloid may serve only to confound this process.[25] There are also a number of studies in which the use of colloid was associated with an *increased* incidence of pulmonary edema.[2,3,13,15] Crystalloids have been administered to patients without deterioration of lung function.[2,3,13,15] In a study of patients with preexisting pulmonary edema, patients receiving crystalloids actually have a statistically greater improvement in shunt fraction compared to those receiving albumin.[13] Some of these studies also suffer from problems in study design. In a study by Weaver, et al.,[15] patients randomized to receive colloid were administered albumin in an attempt to normalize serum albumin. This resulted in fluid overloading in many of their patients. Use of this protocol accounted for many of the reports of adverse effects (i.e. negative inotropy, decreased glomerular filtration, increased coagulopathy) associated with albumin.[16-18] In studies by Moss and Lowe[2,3] patients receiving crystalloids received no greater volumes than patients receiving colloids. This raises the question of whether these two groups were comparable. Generally, greater volume of crystalloids is required to reverse shock.

The gradient of COP minus pulmonary capillary wedge pressure (PCWP) has been suggested in some studies to be a predictor of pulmonary edema.[5,6,8,9] Gradients < 4 have been associated with radiographic evidence of pulmonary edema.[5,6] Colloid proponents suggest administering colloid to prevent dilution of COP. It must be remembered though that factors which increase PCWP may also decrease this gradient. Colloid administration leads to a greater increase in PCWP than crystalloids, which may also be responsible for a decrease in this gradient.

However, the use of the (COP-PCWP) is a gross oversimplification of the formation of pulmonary edema.[13,14,19,25] This relationship neglects comcomitant changes in tissue oncotic and hydrostatic pressures. PCWP although an accurate indicator of left atrial pressures, does not reflect pulmonary capillary hydrostatic pressure.[23] This gradient has also been shown not to correlate with physiologic measures of pulmonary gas exchange.[24]

Colloids versus crystalloids in reversing shock

Shoemaker, Hauser and associates[11,12] have indicated that the addition of colloids increases cardiac output and PCWP, and improves oxygen delivery more effectively than crystalloids alone. The time required to reverse shock was also decreased. Studies conducted by Laks, et al[4] and Rackow, et al[9] also indicated that the addition of colloids lead to a more sustained increase in cardiac output. The major point of controversy surrounding these studies is that the patients receiving crystalloids alone may have been inadequately fluid resuscitated.

A number of studies have also demonstrated that patients can be adequately and safely resuscitated with crystalloid fluids alone.[2,3,13,15] These studies have included severely traumatized patients requiring multiple transfusions[3] and patients with pulmonary edema on entry into the study.[13]

Summary

1. The dichotomous conclusions arrived at by various studies may represent significant investigator bias. Although many studies to date have been prospective and randomized none have been double-blinded. Patients may be over or underhydrated with any fluid combination leading to a less than optimum outcome. It is important to titrate fluids to physiologic endpoints. The use of preset formulas to determine the volume of fluid replacement has been a frequent problem in many of the studies conducted.
2. Although fluid resuscitation has been safely conducted with both crystalloids, colloids, or a combination, most patients can be safely repleted with crystalloids alone. Clinical studies do not consistently support an advantage for the routine use of colloids for fluid resuscitation. Colloids administered are not restricted to the intravascular space, especially in critically ill patient. Fluid replacement with crystalloids can also be accomplished for a fraction of the cost of colloid resuscitation even when increased administration costs are considered.
3. Colloid resuscitation does not require less volume and thus specific patients may benefit from the use of colloids as there are physiologic limits to the compensatory mechanisms that prevent edema formation.[23] These patients include:
   a) Total body fluid overloaded with intravascular volume depletion*
   b) Severely depressed COP*
   c) Unresponsive to fluid resusitation with crystalloids
   *Use hyperoncotic colloid (albumin 25%)

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Proposal for Financing Health Care of the Elderly

AMA BOARD OF TRUSTEES

Summary

Background and Goals

In this report, the Board of Trustees describes the continuing problems with the Medicare program and presents a new approach, developed by the Council on Medical Service and Council on Legislation, for financing health care of the elderly. Previously, interim measures for reform of the current program were approved by the House in Board Reports LL (A-84) and O (I-84). This report also addresses Resolutions 24 and 83 (I-85), which were referred to the Board of Trustees.

The goals of the proposed program are to:

- maintain *access to affordable high quality health care* for the elderly;
- provide for a *prefunded* program;
- provide for *comprehensive protection*, including catastrophic coverage;
- provide for equitable *means testing*;
- provide benefits through the private sector through pluralistic means, with recognition that a *voucher* would provide a beneficiary with a choice of source of coverage;
- allow for *additional contributions to IRAs* for funding supplemental elderly health care expenses;
- provide for *gradual increase in age of eligibility*.

The Board and the two Councils emphasize that the specifics of the proposal outlined in this report represent one feasible combination of elements in the new approach for financing health care of the elderly. The specific elements outlined herein may need to be altered, and can be, once the proposal is under discussion and debate before a wider audience. It may become desirable, for example, to reduce the cost-sharing limit for low-income individuals by increasing the tax rate, or to extend the period of time needed to achieve prefunding.

Current Medicare Program

The current program is headed for bankruptcy. While there are currently about four workers paying taxes to support each beneficiary, by the middle of the next century there will be only two workers for each beneficiary.

According to 1986 Medicare reports, by the late 1990s the Part A trust fund will be totally exhausted. It will be $1 trillion in debt by the year 2010, according to recent estimates by Health and Human Services Secretary Bowen.

The Medicare financing mechanism is flawed. Its pay-as-you-go system creates an intergenerational transfer of resources and is adversely affected by the deteriorating worker-to-beneficiary ratio. Other major flaws of the current system include its lack of catastrophic protection, lack of equitable means testing to keep cost down, and its burdensome government administration.

New Proposed Program

The proposal developed by the Councils and the Board provides *universal eligibility* based on age, and *protects access* through creation of a fiscally and actuarially sound financing approach to achieve *prefunding*.

The proposal provides *catastrophic protection* and *equitable means testing*, with out-of-pocket spending limits for most beneficiaries set at $2,500/year for individuals and $3,750/year for families (i.e., husband and wife). The limits on out-of-pocket spending are reached by combining a uniform coinsurance limit with a deductible that varies in amount in relation to individual or family income.

Following enactment, each eligible individual and family (husband-wife) would receive an *annual voucher* for the purchase of an adequate benefits policy from an approved insurance carrier or other health plan. The voucher amount would differ according to geographic area and would reflect the applicable deductible and coinsurance.

The proposal allows for additional significant contributions to *IRAs* ($500/individual and $1,000/husband-wife), and for tax-free withdrawals from such IRAs for health expenses after reaching eligibility age.

There would be a *gradual increase in age of eligibility* for benefits under the new program from 65 to 67, at the rate of three months per year.

The new program would be financed by eliminating the

This is a report of the AMA Board of Trustees to the House of Delegates, June 1986.

current 1.45% payroll tax on employees and replacing it with an initial tax of 1.75% on adjusted gross income up to $100,000. For about 95% of individuals, this would mean a net increase of .3 percentage point in their tax obligation. The payroll tax on employers would be continued, with a modest (less than 1 percentage point) increase in the current 1.45% rate. Although the initial tax rates for both employers and individuals under the Councils' proposal are slightly higher than existing rates under the Medicare program, the future rates for the new program are considerable less than those combined payroll and general revenue taxes (and Part B premium costs) which would be needed in the future to fund the current Medicare program on a fiscally sound basis.

Introduction

Even the current economic upturn and increased constraints on federal spending, serious Medicare solvency problems are projected for the future. Intermediate projections have estimated that, without significant program modifications, the Hospital Insurance (HI) trust fund reserves will be exhausted by the late 1990s. The Secretary of Health and Human Services recently predicted that the program will be one trillion dollars in debt by the year 2010. This projected Medicare fiscal crisis has generated a series of proposals that address elderly health care financing. Generally, the proposals fall into categories that:

- maintain but reform the current Medicare program, by increasing revenues, reducing providers' fees and charges, and limiting the utilization of medical services;
- restructure the Medicare program with operational and financing innovations (such as a voucher system or a health individual retirement account system) that are designed to either supplement or replace Medicare altogether.

In adopting Board of Trustees Report LL (A-84), the House of Delegates approved recommendations for interim changes in the current Medicare program. These changes were designed to maintain fiscal solvency while more basic reforms in the program were being developed.

The proposal detailed in this report, which calls for basic restructuring of health care financing for the elderly, is the product of careful study by the Board, the Council on Medical Service and the Council on Legislation. It is designed to eliminate the inherent weaknesses of Medicare's current pay-as-you-go financing mechanism, which relies on intergenerational transfer of income from the working young to subsidize health care for the elderly. The new proposal largely eliminates these cross-generational transfers and minimizes the fiscal impact of the major population shift from the current four workers per Medicare beneficiary to a little over two workers per beneficiary that will occur over the next 60 years.

This proposal draws from and expands on certain basic principles set forth by the AMA in Board of Trustees Report LL (A-84), and is consistent with those principles. This proposal would:

- Assure access to affordable high quality health care for the elderly.
- Assure sound mechanisms for financing health care of the elderly, with responsibility shared by the federal government, providers and beneficiaries.
- Assure fiscal and actuarial soundness.
- Provide comprehensive benefits, including catastrophic health care expense coverage.
- Provide for different levels of beneficiary cost-sharing based on ability to pay.
- Allow free choice by beneficiaries among private plans providing specified adequate benefits.

The proposal which follows describes a program for elderly health care financing which is consistent with these principles:

Proposal for Financing Health Care of the Elderly

Any proposal which contemplates elimination of the current Medicare program must be established in a way which honors commitments already made to the elderly.* The proposed program calls for contributions during working years in an amount sufficient to *simultaneously fund future health care for those now working and contributing and, initially, defray similar health care costs for those now on Medicare* (these latter costs will decrease over time to zero). In brief, this proposal:

- creates a publicly managed trust fund reserved for the individual's purchase of private health insurance in old age;
- immediately eliminates the health insurance (HI) payroll tax on individuals and replaces it with a flat tax rate on adjusted gross income up to $100,000. The tax rate is based on the actuarial costs of accumulating a fund for the provision of health insurance providing specified adequate benefits on retirement for those now working and for those now retired;
- immediately eliminates the federal government's general revenue obligation to the Supplementary Medical Insurance (Part B) trust fund, which totaled about $18 billion in 1985;
- provides vouchers for private health insurance initially at age 65 (increasing to 67). The amount of the annual voucher will vary based on regional health cost differences and beneficiary income;
- establishes actuarially sound financing of benefits;
- promotes private provision of health insurance and medical care; and
- allows additional tax-exempt savings beyond the pre-

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*The current Medicare program also includes coverage for the disabled and those with end stage renal disease (ESRD). These groups constitute two separate and distinct classes of Medicare beneficiaries, in both fiscal and actuarial terms. Therefore, financing for these individuals should be kept separate from the new program for the elderly. It is recommended that separate funding be provided for care of *non-elderly* disabled and ESRD patients. For example, such services might be made one of the required services under state Medicaid programs, or there might be funding from general federal revenues. Care of *elderly* disabled and ESRD patients would be included under the new program.

sent IRA limits. IRA withdrawals in any amount after eligibility age would be tax-exempt if used for health expenses. Such health expenses would include deductibles and coinsurance under the private plans offered, and long-term care.

A more detailed description of the proposal is set out below.

A. Program Structure

Every year, all individuals up to age 65 (increasing to age 67 in three-month per year increments) will be taxed a certain percentage of their adjusted gross income. These revenues will be directed to an independent federal agency, the Elderly Health Financing Agency (EHFA). This agency will be responsible for providing vouchers for the purchase of health insurance for the elderly.

EHFA will be an independent body of the federal government, similar to the Federal Reserve Board. It will be charged with managing accumulated funds to generate interest and investment income and with disbursing the funds. *Its primary function is to operate as a "pension" fund for the accumulation of assets for the purchase of health insurance in old age.* A more detailed description of the EHFA and its functions is given in Appendix 1.

On an ongoing basis, EHFA would have the following additional responsibilities:

1. To determine, in consultation with the public and providers, the adequate level of health care benefits, including limits on out-of-pocket spending for the elderly.
2. To determine the actuarially sound premium needed to purchase qualified private health insurance for the elderly in the various areas of the country.
3. To determine the necessary employer and individual tax rates to fund the program.
4. To continuously evaluate financing mechanisms and contribution rates in light of demographic or economic changes, and make any adjustments needed to preserve fiscal solvency of the program.

The following sections of this proposal identify the scope of health insurance benefits and a financing mechanism which the Board and the two Councils believe presents *one equitable* combination of elements in creating a program to remedy deficiencies in the current Medicare program.* The proposal presents a reasonable balance between the benefits provided and the tax rate needed to fund these benefits. It also affords immediate federal savings through eliminating the general revenue obligation to Part B. It will assure access to needed health care by the elderly on an ongoing basis.

B. Benefits

After enactment of the program, all individuals 65 and over will be provided with an annual voucher of an amount sufficient to purchase an individual private health insurance policy providing at least the adequate benefits specified in Appendix 2. This plan would replace the benefits currently provided under both Parts A and B of Medicare. The voucher amounts would vary with regional health care cost differences, but *not* with age, since insurers would be underwriting the eligible population as a group. To reflect improving life expectancy, age of eligibility will be increased to 67 over an eight-year period, in three-month per year increments.

The required adequate benefits are those approved by the AMA in Council on Medical Service Report H (I-83), with two exceptions. First, benefits not needed by the eligible population, such as obstetrical care, are eliminated. Second, in recognition of the relatively favorable economic status of many older persons,** the amount of beneficiary cost-sharing for covered services varies with the adjusted gross income of the beneficiary, as also shown in Appendix 2.

Most *individual* beneficiaries would have a cost-sharing limit of $2,500 for covered services ($500 deductible and 80/20 coninsurance for the remaining $2,000), and most *families* a limit of $3,750 ($750 deductible and 80/20 coinsurance for remaining $3,000). The amount of the *deductible* for both individuals and families would be increased by 10% of the amount of adjusted gross income above $30,000, and 15% of the amount above $50,000 (in multiples of $5,000). Coinsurance would remain the same regardless of income. Beneficiary spending on all covered services would apply toward the deductible and coinsurance. Once the cost-sharing limit was reached, the plan would pay 100% of covered expenses, with no maximum limit. To implement this "means testing" of benefits, voucher amounts would vary according to the cost of a plan with the applicable deductible, as well as with regional health cost differences. (All cost-sharing and yearly income limits would be indexed to general cost-of-living increases).

Appendix 3 shows the amount of beneficiary out-of-pocket expense for covered services under the new program versus the present Medicare program, for hospital stays of varying duration.

Even though the program will have provision for substantial cost-sharing based on income, most individuals will not experience major new out-of-pocket spending. In fact, the cost-sharing increase is relatively modest for the average beneficiary. Analysis of Health Care Financing Administration data indicates that the average user of Medicare benefits spent about $700 out-of-pocket during 1985 on coinsurance and deductibles for Medicare covered services. Independent actuarial analysis indicates that the average premium cost of a wrap-around policy to completely cover the $2,500 individual cost-sharing limit under the new program would be about $1,400. Subtracting the approximately $200 no longer needed for Part

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*The Councils recognize that variations in elements of the program, such as means testing, tax rates and apportionments, and the date at which prefunding is achieved, could also reach the Association's objectives. The program outlined here illustrates one such approach.

**Mean income of individuals over 65 in 1983 was $10,094, compared to $13,973 for those 15 to 65.

B premiums would leave the average Medicare enrollee in most cases with an increased out-of-pocket liability for covered services of only $500 a year (for the wrap-around insurance) under the new program—a program which provides substantially increased protection against catastrophic expense.

C. Premium Costs

Independent actuarial analysis indicates that the annual premium cost (in 1986 dollars) of a private health insurance policy with adequate benefits for those 65 and over would be $1,700 in a low health cost area, $2,073 in a medium cost area, and $2,445 in a high cost area. The grouping of states by high, medium and low health cost areas is shown in Appendix 4. There will be further variation in premium cost between states in a given grouping. These premium estimates include a 10% "loading" for marketing, administration and other private insurer costs.

D. Program Funding

Under the proposal, the present HI payroll tax of 1.45% on employees would be eliminated at the inception of the new program and replaced with a tax on adjusted gross income up to $100,000 a year (but excluding the lowest 5% of earners from the tax). This cap amount would be indexed to inflation. Use of a $100,000 cap on individual income taxed under the new program is intended to reduce to some extent the income transfer within generations occurring under the new program.

The HI payroll tax on *employers* would be retained, with a modest (less than 1 percentage point) increase in the employer tax rate of a magnitude sufficient to provide one-half of the required revenue for the new program. The earnings base subject to the employer tax would remain as provided in the current law (currently $42,000, subject to automatic increases).

Actuarial analysis has identified the tax rates on individual income which are needed to:

(a) meet costs of vouchers for all individuals eligible for benefits under the new program in 1986 and each year thereafter; and

(b) by the year 2016, accumulate sufficient reserves in the EHFA fund to cover both *all future costs for beneficiaries then on the program*, and *the accrued liability for all those below eligibility age who had contributed to the program*. By 2016, true *prefunding* of benefits would be accomplished, in that all tax contributions made are *preserved* for the future use of those contributing them, and earn interest during contributing years, rather than being paid out immediately for beneficiaries then on the program.

These tax rates are displayed in the first two columns of Table 1. To reduce undue financial impact on contributors, the tax rates proposed are incremental in nature. They begin at levels only slightly above the current 1.45% HI payroll tax on individuals, and slightly above the amount needed to pay benefits for current beneficiaries, and rise to a peak in 20 years (2006), after which they would drop to a constant and continuing rate sufficient to achieve full prefunding ten years later (2016). The tax rate increase over the first 20 years is needed for three reasons:

- To meet obligations to those currently on the program who have not "prefunded" their own benefits.
- To simultaneously begin the accumulation of reserves for those currently contributing.
- To minimize the fiscal impact of the shift in number of workers per beneficiary that will occur by the middle of the next century, from 4:1 to a little over 2:1. The proportion of workers-to-beneficiaries is projected to remain relatively constant after that time.

Table 1
FISCALLY SOUND INDIVIDUAL TAX RATES TO FUND PROPOSED PROGRAM AND PRESENT MEDICARE PARTS A AND B

	New Program*		Medicare A & B**	
	Stabilized Medical Inflation		*Intermediate*	*Pessismistic*
	4.0%	5.5%	(Alt.II B)	(Alt. III)
1986	1.75%	1.75%	2.17%	2.25%
2006	3.55%	3.55%	3.15%	4.87%
2007	1.16%	2.33%	3.37%	5.10%
2035	1.16%	2.33%	5.85%	12%
2060	1.16%	2.33%	5.85%	12%

The economic assumptions underlying these proposed tax rates are conservative. They include:

- alternate stabilized rates of 4% and 5.5% medical care cost inflation (after 2000 and 1995, respectively);
- 4% annual CPI inflation;
- 6.5 stabilized (after 1995) interest on funds;
- 5.5% yearly increase in wages.

As indicated in Table 1, assuming that medical care inflation stabilizes at 5.5%, an initial tax rate of 1.75% on individual adjusted gross income up to $100,000 (in 1986 dollars) would be required in 1986. This amount would rise in increments of .09 percentage point yearly to a maximum of 3.55% in 2006, after which it would drop to a continuing rate of 2.33%.

If medical care inflation is stabilized at 4%, the same as CPI inflation, then the ultimate individual tax rate would be lowered to 1.16%.

Thus *for most individuals* (about 95% of persons with income earn less than the current $42,000 HI payroll tax base), the *net* increase in their taxes in 1986 will be .3

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*As noted previously, program revenue from a continuing payroll tax on employers at a tax rate sufficient to provide one-half the required new program revenue is also assumed in calculating these rates.

**Rates on individuals; similar but slightly lower rates on employer would continue; these rates are an extrapolation based on the 1985 Report of the Medicare Board of Trustees. The 1986 Report contains slightly more pessimistic projects concerning such rates.

percentage point (i.e., 1.75% less the discontinued 1.45% employee payroll tax).

To further put these tax rates in perspective, it is helpful to compare them with the estimated individual tax rates which would be necessary to defray projected future costs of both Parts A and B of the current Medicare program over the same time frame. Social Security Administration actuaries have calculated the percent of taxable payroll needed just to pay current Part A benefits and maintain a minimal trust fund reserve for the period 1985-2059. Extrapolating these figures to also include Part B costs (which are approximately 50% of Part A) results in tax rates shown in the third and fourth columns of Table 1.

These are the approximate rates that individuals would pay on the present earnings base to create funding for a continuation of present Medicare Part A and B. They are made up of an increasing HI payroll tax, Part B premiums, plus general revenue taxes which fund the present general revenue contributions to Part B. They assume a similar although slightly lower employer payment (i.e., the *combined* employer-employee tax rate would be almost twice the amount shown).

These Medicare tax rates are derived from the SSA actuaries' intermediate set of assumptions (alternative IIB) and are similar to the assumptions used in calculating tax rates needed under the new program (at the 5.5% ultimate medical inflation rate). Thus, the two middle columns in Table 1 are based on comparable assumptions. Rates based on the SSA's pessimistic assumption (alternative III) are also given.

As indicated in the two middle columns of Table 1, individual tax rates for the new program are lower than those required to adequately fund the current Medicare Parts A and B in 1986, slightly higher in 2006, and significantly lower in 2007 when they drop to a stable continuing rate of 2.33%. The required individual rates for Medicare benefits continue to rise beyond 2007, however, to a level of 5.85% in the year 2035 and beyond. *On an ongoing basis, therefore, the new program requires less taxes than maintaining current Medicare benefits, while achieving prefunding of elderly health care expense on a fiscally sound basis as well.*

As noted previously, under the new program the employer HI tax on the present earnings base would be retained and the tax rate increased in an amount sufficient to provide one-half the required revenue. The initial employer tax increase in 1986 would be less than 1 percentage point—from 1.45 to 2.21. The employers' tax rate for the additional years shown in Table 1 would be in most years less than they would pay to fund continuation of present Medicare Part A and B benefits. The employer rates for the new program would be 4.49% in 2006, but would drop to 2.95% in 2007 and thereafter.

Ultimate tax rates on both individuals and employers are significantly lower under the new program because (a) investment income is derived from the reserves accumulated, and (b) there is increased beneficiary cost-sharing related to income. Tax rates are slightly higher under the new program in 2006 because of the need to meet obligations to current elderly who have not prefunded their own benefits, and simultaneously begin the accumulation of reserves for those currently contributing. Both tax rates level off (with Medicare's at a significantly higher level) once the demographic shift in proportion of workers to beneficiaries has leveled off.

E. Vouchers for Health Insurance Coverage

The EHFA would require all qualified commercial insurers, Blue Cross/Blue Shield plans and other health plans to accept all individuals of eligibility age regardless of their health status. In essence, this would create a group plan for the elderly. At eligibility age all individuals will know that there is an actuarially sound trust fund which will provide for their lifetime an annual voucher for the purchase of health insurance providing at least the adequate coverage.

Whether a person dies before or after age 65, his or her contributions remain with the EHFA to reduce the actuarial costs of those surviving. *The purpose of this program is not to provide an estate, but an actuarially sound fund to provide for purchase of health insurance in old age.*

F. Additional IRA Savings

The concept of a health individual retirement account (HIRA) is attractive because of its reliance on private markets and its voluntary nature. Accordingly, this concept received thorough evaluation in the study by the Board and the Councils. Most HIRA proposals advanced to date work as follows: tax incentives are provided to individuals to encourage and enable them to open private HIRAs during their working years. The accumulated funds are then used for the purchase of health care and/or private health insurance in old age. Such HIRAs are designed to be used alongside Medicare, which would continue to provide funds for health care to individuals who did not open HIRAs or to those who require coverage for catastrophic illness. Besides the substantial tax incentives to encourage HIRAs, these proposals permit unspent portions in the accounts to revert to the individual's estate at death.

Based on their study, the Board and the Councils are convinced that use of an IRA can be a useful *supplement* to Medicare. However, as a potential *alternative* to Medicare this approach creates a new set of problems in funding health care of the elderly. Under a voluntary HIRA approach as an alternative to Medicare, funds would still be needed to provide health care for those who cannot afford to or choose not to open HIRAs, or to supplement that portion of the HIRA accounts which is insufficient to cover the level of health care deemed necessary. Even more importantly, the private HIRA concept is not compatible with design of a program which seeks to provide the same range of benefits to all of the elderly without variation in the amount of out-of-pocket expenses because of geographic location.

Accordingly, this proposal does not recommend the establishment of new mandatory or voluntary private HIRAs as the sole or principal means for financing health care expense of the elderly. *The Board does recommend the expansion of the existing IRA mechanism to provide supplemental funds for health care expense on retirement.* From the inception of the program, all individuals would be allowed to contribute an additional tax deductible amount of $500 (and $1,000 for husband/wife) to the present amount allowed for IRAs. The contribution limits might be adjusted annually.

After attaining eligibility age, any funds withdrawn from such IRAs *for health care expenses* would be tax-free. In addition, individuals below eligibility age who become permanently and totally disabled could also withdraw funds for health care expenses tax-free. Eligible health expenses would include (but not limited to) health insurance premiums for "wrap-around" coverage of deductibles and coinsurance, direct payment of such cost-sharing amounts, or expenses of long-term care.

As at present, individuals could also elect not to withdraw their IRA funds but preserve them for their estate if desired. Any funds remaining in an IRA on an individual's death would revert to that person's estate.

G. Additional Program Characteristics

In addition to achieving the major goals specified earlier, the program has several implications which may not be immediately evident:

- General inflationary increases in health care costs for old age are built into the program, without the need for government intervention. This is done in the following manner:
  a. Any funds placed in the EHFA trust fund accumulate interest based on actual rates. As inflation increases, the rate of interest increases proportionately, and additional interest accumulates at rates similar to the increase in the general level of prices.
  b. Since annual contributions are based on a tax rate on adjusted gross income up to an automatically indexed amount (initially $100,000), the annual contributions will increase with the rate of inflation. For example, a 10% rate of inflation will increase incomes. The income cap and annual contributions will also increase by 10% to keep up with that portion of health care costs affected by inflation. As a result, there is no need to keep readjusting the tax rate to account for inflation once the program has achieved prefunded status.
- Business cycle effects are moderated in accruing the funds. Since funds are collected over the individual's working lifetime, decreases in contributions when incomes fall are made up during periods of growth. Since business cycles generally last between 5 and 10 years, the extended contribution period should be sufficient to average out business cycle effects.
- There are three situations in which EHFA may have to intervene to assure that sufficient funding is provided for the adequate level of benefits:
  a. Changes in the definition of the adequate level of benefits.
  b. Future major demographic changes in birth rates, death rates or life expectancy.
  c. Changes in the rate of medical care inflation in relation to general inflation.

  Interventions to adjust for these changes may take the form of adjusting the tax rate, and/or changing the eligibility age.
- EHFA must be insulated from executive and/or legislative interference. A model based on the Federal Reserve Board can be employed. In this way, the modifications proposed do not constitute a radical departure from current political institutions. As noted previously, specifications as to the composition, responsibilities and operation of the EHFA are given in Appendix 1.
- EHFA will have the fiduciary responsibility to invest its funds in a manner which will insure sufficient earnings on assets and sufficient cash flows.

Resolutions 24 and 83 (I-85)

As part of their development of a proposal for elderly health care financing, the Board and the two Councils gave careful consideration to two resolutions dealing with restructuring of the Medicare program, which were referred by the House of Delegates at the 1985 Interim Meeting.

- "Resolution 24 called upon the AMA to endorse and support the Health Care Bank/IRA concept, and to convene a nationwide conference devoted to exploring and promoting the merits of this method."
- "Resolution 83 asked that the AMA support the basic concepts of HR 3505, regarding funding of health care for the elderly by establishing an income tax credit for amounts contributed to health care savings accounts and by providing a higher Medicare deductible and protection against catastrophic medical care expenses for individuals who have established such accounts, and to develop a supplement to the Medicare program that will relieve some of the fiscal pressures on the program while affecting in a positive way both the cost and level of health care benefits provided to the elderly."

The Board and the Councils believe that the proposal contained in this report is responsive to the concerns expressed in both resolutions. The proposal supports the use of the IRA mechanism as a supplemental source of funding health care expense for the elderly; if adopted by the House, the Board plans extensive discussion of this proposal also calls for tax incentives to use IRAs as a source of savings for health care expense, and for increased initial deductibles coupled with catastrophic expense protection, as suggested in Resolution 83.

Conclusion

This report has presented a proposal by the Board of Trustees, Council on Medical Service and Council on Legislation for elderly health care financing which replaces the Medicare program. Recognizing that Medicare has serious limitations, this plan attempts to correct those deficiencies by basing the new program on a set of actuarially and fiscally sound principles.

Under the proposed program universal access for financing an improved level of health care benefits can be achieved with significant long-term reductions in revenue requirements. Furthermore, this health care will be self-funded, with no need for general revenue funds from the federal government. The provision of insurance and health services will be from the private market, thus reducing government intervention.

The Board of Trustees has approved the program goals and concepts presented in this report, with recognition that modifications in program details may become appropriate in future discussions. The Councils will continue their active involvement in this process. If approved by the House, the Board plans wide dissemination of the report to executive and legislative branches of the federal government, other concerned groups, and the public.

Recommendation

The Board of Trustees recommends approval of this report in lieu of Resoltuions 24 and 83 (I-85).

Appendix 1

Elderly Health Financing Agency: Proposed Structure

To provide for an agency free from unnecessary executive and/or legislative interference, it is proposed that the Federal Reserve Board model be adopted.

The Board of Governors of the Federal Reserve System ("Board") is composed of seven members, appointed by the President with the advice and consent of the Senate, for 14-year terms.

The members of the Board are ineligible during the time they are in office and for two years thereafter to hold any office, position, or employment in any member bank. The restriction, however, does not apply to members who serve the full term of their appointment. Of the persons appointed to the Board, one is designated by the President (with the consent of the Senate) to serve as Chairman, and another as Vice Chairman, both for a term of four years. The Chairman of the Board serves as its active executive officer. The principal offices of the Board are in Washington, D.C.

This model can be applied to the Elderly Health Financing Agency. By expressly delegating certain powers to this proposed Agency, Congress can assure that the Agency has the freedom to act with relative independence. The Agency could be composed of eight to ten presidential appointees that have been approved by the Senate. While regional appointees are probably not necessary, it is important that there be representation on the agency from business, labor, physicians, hospitals, payors and the public.

The term of office for each appointee and the salary could be determined as further details regarding the Agency are developed. (For example, it would probably be advisable to stagger terms for the initial appointees rather than specifying the same terms for all.) Overall, however, the important consideration will be drafting legislation which specifically delineates the Agency's authority and guarantees the exercise of independent judgment.

The following functions and powers would be expressly delegated by Congress to the EHFA.

1. Determine, in consultation with the public and providers, the adequate level of health care benefits required to be offered by participating plans, including limits on out-of-pocket spending.
2. Determine the actuarially sound premium needed to purchase adequate benefits health insurance.
3. Determine the average annual contribution needed over a specified number of working years to provide a fund sufficient for purchasing the required insurance.
4. Based on the needed annual contribution and the current income distribution of the contributing population, propose to Congress any necessary changes in tax rates.
5. Serve as the custodian of collected contributions and invest such contributions in compliance with applicable restrictions concerning asset placement imposed on current pension funds or federal investment programs. The legislation creating the overall program should specifically prohibit the use of any of the monies in the EHFA fund for any purposes other than intended under the program.
6. Provide mechanisms to oversee the operation of insurance companies or other health plans offering coverage to the elderly with respect to provision of required adequate benefits, enrollment, marketing and advertising practices, and certify such plans for participation in the program. EHFA standards regarding these aspects of plan operation would override conflicting state requirements.
7. Monitor the rate of increase in health care costs relative to inflation generally, and changes in life expectancy and birth rates. Propose to Congress any needed adjustments in either the tax rate, age limits for tax contributions and/or age of eligibility.
8. Based on changes in mortality, morbidity, medical science or patterns of health care, propose to Congress, after consultation with the public and providers, any appropriate modifications in the definition of required adequate benefits.
9. Based on regional health cost differences, delineate the geographic areas to be identified with

respect to differing voucher amounts, and annually set the voucher amount for each area.

10. Disburse vouchers for purchase of private health insurance to beneficiaries.

Appendix 2

Required Benefits for Policies Under New Program

I. Services Covered

A. Diagnostic, Therapeutic or Preventive Medical Services Provided by or Under Direction of Licensed Physicians in the Office, Hospital or Other Setting

1. Diagnosis and medical or surgical treatment of illness or injury
2. Psychiatric care
3. Diagnostic x-ray and laboratory services
4. Radiation therapy
5. Consultation
6. Periodic medical examinations; every 2 years
7. Immunizations which are cost-effective for the benficiary group covered

B. Emergency and Outpatient Services for Physical and Mental Illness

1. Outpatient diagnostic services (x-rays, lab tests, etc.)
2. Use of operating, cystoscopic, cast rooms and supplies
3. Use of emergency room and supplies for emergencies
4. Ambulance services
5. Treatment for alcoholism

C. Inpatient Hospital Care for Physical and Mental Illness

1. Bed, board and nursing services
2. Drugs, oxygen, blood, biologicals, supplies, appliances and equipment used in the facility
3. Operating, recovery room charges; intensive, coronary, special care, rehabilitation unit charges
4. Diagnostic services (x-rays, laboratory tests, EKGs, etc.)
5. Physical, occupational, speech therapy

D. Inpatient Skilled Nursing Facility Care for Physical and Mental Illness

1. Bed, board and skilled nursing
2. Physical, occupational, speech therapy
3. Drugs, biologicals, supplies or equipment used in the facility

E. Home Health Services by a Certified Home Health Agency as Ordered by a Physician

1. Nursing care
2. Physical, occupational, speech therapy
3. Medical supplies and appliances (other than drugs and biologicals)
4. Rental of durable medical equipment
5. Oxygen, blood, biologicals

II. Beneficiary Cost-Sharing

Variable out-of-pocket limit, keyed to household income as follows:

For an individual: *Deductible*=500 +10% of adjusted gross income between $30,000 and $50,000 and 15% of adjusted gross income above $50,000

Coinsurance=$2,000 (regardless of income)

For a Family: *Deductible*=$750 + 10% of adjusted gross income between $30,000 and $50,000 and 15% above $50,000

Coinsurance=$3,000 (regardless of income)

- For most beneficiaries maximum out-of-pocket expenses would be:
  - $2,500/year individual
  - $3,750/year family (i.e. husband and wife)
- Annual out-of-pocket limits would include incurred expenses of the last two months of the prior year.
- Deductibles could be met through hospital, physician and other allowed health services.
- Beneficiary coinsurance would be no more than 20%.

Illustration of How Variable Out-of-Pocket Limits Would Apply*

Adjusted Gross Income	15,000	20,000	50,000	100,000	150,000
Individual					
Deductible	500	500	2,500	10,000	17,500
Coinsurance	2,000	2,000	2,000	2,000	2,000
Out-of-pocket limit	2,500	2,500	4,500	12,000	19,500
Family					
Deductible	750	750	2,750	10,250	17,750
Coinsurance	3,000	3,000	3,000	3,000	3,000
Out-of-pocket limit	3,750	3,750	5,750	13,250	20,750

III. Other Program Features

There would be no maximum limit—either lifetime or per episode—on the amount paid by the plan for covered expenses in the catastrophic portion of coverage.

In paying for physicians' services, the amount allowed toward meeting the beneficiary's cost-sharing limit would be the difference between the plan payment and the 90th percentile of physicians' customary or median charges in the area (the amount which would cover the customary or median charge for a service at least 90 percent of the time it is performed). Once the cost-sharing limit was reached, the plan would pay the 90th percentile of customary charges in full. The plan would continue to pay for hospital expenses on a service basis, with contractually specified beneficiary cost-sharing being applied toward the cost-sharing limit.

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* The great majority of beneficiaries will have their out-of-pocket spending limited to $2,500. Wrap-around coverage would be available to insure against out-of-pocket limits for all beneficiaries, including those at higher income levels.

Appendix 3

Comparison of Beneficiary Out-of-Pocket Expense for Covered Services: New Program vs Present Medicare

Assumptions: Hospital charge = $492/day
One surgical procedure = $500
Physician visits = $20/day

	New Program	*Medicare*
7 Days Hospital Stay	$1,217	$ 680
14 Days	$1,906	$ 708
21 Days	$2,500	$ 736
59 Days	$2,500	$ 888
72 Days	$2,500	$ 2,440
75 Days	$2,500	$ 2,827
89 Days	$2,500	$ 4,633
149 Days	$2,500	$18,273

The average user of Medicare benefits spent about $700 out-of-pocket during 1985 on Medicare-covered services. Average premium cost of a "Medigap" policy to cover the $2,500 cost-sharing limit under the new program is $1,400. Net additional out-of-pocket liability for covered services to the average beneficiary who purchases such "Medigap" coverage is therefore $500 ($700 less $200 no longer required for Part B premiums).

Appendix 4

Division of States and Territories Into Low, Medium and High Cost Areas

Average Medicare costs in low cost areas are 82% of overall cost.

Average Medicare costs in medium cost areas are 100% of overall cost.

Average Medicare costs in high cost areas are 11.8% of overall cost.

Low Cost Areas	*Medium Cost Areas*	*High Cost Areas*
Alabama	Arizona	Alaska
Arkansas	Colorado	California
Georgia	Conncticut	Dist. Columbia
Idaho	Delaware	Illinois
Kentucky	Florida	Maryland
Maine	Hawaii	Massachusetts
Mississippi	Indiana	Michigan
Montana	Iowa	Missouri
New Hampshire	Kansas	Nevada
New Mexico	Louisiana	New York
No. Carolina	Minnesota	Rhode Island
No. Dakota	Nebraska	Guam
Rhode Island	New Jersey	
So. Carolina	Ohio	
So. Dakota	Oklahoma	
Tennessee	Oregon	
Utah	Texas	
Vermont	Virginia	
Washington	Wisconsin	
W. Virginia	Wyoming	
Puerto Rico		
Virgin Islands		

Appendix 5

Assumptions Underlying Proposal, and Data Sources Utilized

A. Assumptions

1. Current employer-provided health insurance benefit plans for retirees and workers over Medicare eligibility age have been disregarded in establishing required adequate benefits under the new program, on the assumption that these plans would be modified with inception of the new program.
2. Premium costs for private plans include additional 10% "loading" over Medicare costs, for administrative and marketing expense.
3. Long-range Medicare cost estimates prepared by the Social Security Administration are based on valid assumptions and methodology, and have been utilized where appropriate.
4. Financing for care of the permanently and totally disabled and ESRD patients under 65 (and ultimately, under 67) would be provided through other programs. Over-65 (over-67) disabled and ESRD patients would be covered under the new program.
5. Adjusted gross income up to $100,000 and excluding income for population in bottom 5% of current U.S. income distribution is base used to calculate individual tax rates for new program. Limits on income subject to taxes would be indexed.
6. Total adjusted gross income under $100,000 utilized in calculations is 117% of total wage income under this amount.
7. Assumptions concerning interest earned on funds, medical inflation, and increases in wages and CPI are as follows.

Year	*Interest on Funds*	*Medical Inflation*		*Wages*	*CPI*
		I	*II*		
1985	10% (5 yrs)	7.5%	7.5%	5.5%	4.0%
1990	8.5% (5 yrs)	6.0%	6.0%	5.5%	4.0%
1995	6.5%	4.5%	5.5%	5.5%	4.0%
2000 & After	6.5%	4.0%	5.5%	5.5%	4.0%

B. Data Sources

1. *Required Adequate Benefits:* Council on Medical Service Report H (I-83).
2. *Premium Costs of Proposed Plan:* Computations by Wyatt and Company, Consulting Actuaries, from claim distributions by size and benefit of employer post-retirement benefit plans and Medicare data.
3. *Medicare Costs for Part A and Part B Benefits, by States, and by Age Cohorts:* Medicare cost data.
4. *Wage Distributions (Households and Individuals):* Bureau of Census; Special Studies.
5. *Population Projections to Year 2060:* Social Security Administration.
6. *Relationship of Taxable Payroll, Covered Payroll, Total Payroll:* Mr. Eli Donkar, Actuarial Division, Social Security Administration.

Reflections on Medicine

Is There No Difference?

ROBERT U. MASSEY, M.D.

Recently *Science* published a lead article, "Medicine as Business: Are Doctors Entrepreneurs?"[1] Most of it consisted of an abridged and edited exchange of letters between Arnold Relman, editor of *The New England Journal of Medicine*, and Uwe Reinhardt, professor of economics at Princeton. The question asked by Dr. Relman was the critical one: "Does the concept of profession, as applied to physicians and other health care professionals, have any meaning in our society and, if so, does that meaning imply ethical obligations for health professionals which do not apply with equal force to businessmen?"

"You ask me again," wrote Professor Reinhardt, "whether I truly see no differences between physicians and other purveyors of goods and services. Honestly, Bud, I don't."

This correspondence has been published as part of the study recently completed by the Institute of Medicine, *For-Profit Enterprise in Health Care*. As Barbara J. Culliton, writing for *Science*, says, "Their correspondence provides a framework for the debate that will no doubt continue for years to come." It indeed goes straight to the heart of the matter.

It is not difficult to see how an economist, looking at what even some of us have come to call "the health care industry," would observe all of the elements of a commercial enterprise with its ultimate concern for the "bottom line," whether that means profits for the investors, earnings for physicians, or excess of income over expenditures for hospitals. Health care, as distinguished from medical practice, has become so like big business, with its marketing, advertising, and competing, that it is essentially indistinguishable from any other business enterprise.

This is not the way we doctors have seen our work, nor is it the way we have wanted to see it; perhaps we have been deceived by our idealism, and since most of society shared that idealism, we may have been blind to what we have really been up to. Is the idealism merely part of some cynical marketing strategy, or does it have an objective basis, discoverable in the nature of the work and in the need for trust within the relationship between physician and patient?

Even first year medical students, unsophisticated in the issues around what Eli Ginzberg, another economist, has termed "The Monetarization of Medical Care," have observed that the physician and patient have a special relationship closely analogous to that of parent and child, one which imposes obligations far beyond those between seller and buyer. *Caveat emptor* is not expected to apply in the clinic and at the bedside.

Physicians have sometimes seemed impatient with formal ethical reasoning, probably because they suspected that the roots of their ethics lay deeply imbedded in medicine itself, and that good medical care depended upon virtuous practitioners of the art. Biomedical science rests upon the honesty inherent in all science. Medical technology and skill fail without the honesty of good craftsmanship in which the worker serves the work. In both science and technology, as well as in art, the end is the work itself. The English writer of detective stories, Dorothy L. Sayers, once said that

> ". . .the moment you think of serving other people, you begin to have a notion that other people owe you something for your pains; you begin to think that you have a claim on the community. You will begin to bargain for reward, to angle for applause, and to harbour a grievance if you are not appreciated. But if your mind is set upon serving the work, then you know you have nothing to look for; the only reward the *work* can give you is the satisfaction of beholding its perfection. The work takes all and gives nothing but itself; and to serve the work is a labour of pure love."[2]

Finally in medicine there is the unique bond of trust in which the patient rests completely confident that only his or her best interests matter; the physician comes to sense the grave obligation imposed by this trust.

It may be possible to express all this in the words of economics, or to claim that the truth inherent in science, the honesty in good craftsmanship, and the trust in the relationship between doctor and patient apply to the work of all purveyors of goods and services, and are not unique to medicine. Honestly, I doubt it.

REFERENCES

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2. Sayers DL: Creed or Chaos? Harcourt, Brace and Company, New York pp 60-61, 1949.

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The Therapist's Dilemma: Respect Confidentiality or Warn Potential Victims?

JOSEPH M. HEALEY, J.D.

In many areas of health law, rights of various parties are in conflict and the precise boundaries of competing duties uncertain. Resolving such conflicts and clarifying such ambiguities often involves balancing the competing interests in a manner that minimizes harm rather than maximizes benefit. Such balances are not easily established in complicated situations such as those in which a mental health professional obtains evidence of a patient's intent to harm a third party. How should the therapist balance the duties of beneficence and confidentiality toward the patient with the duty to warn or protect innocent potential victims? A recent Vermont case[1] addressed these issues and provides a focus for a re-examination of the therapist's duties in such cases.

John Peck, a 29 year old who lived at home with his parents, had an argument with his father on June 20, 1979. In the course of the argument, his father called him "sick" and "mentally ill" and told him he should be hospitalized. John left home and went to the Counseling Service of Addison County, a nonprofit mental health agency. John had attended therapy sessions with the same therapist there between September 1976 and October 1977. From October 1977 until June 1979, he was not a patient of the Counseling Service. The therapist arranged for John to stay at the home of John's grandparents and scheduled a counseling session for the next day. At that session, John expressed anger at his father. At a second session on June 26, John told the therapist that he wanted to get back at his father. In response to the therapist's inquiry about how he would get back at his father, John stated, "I don't know, I could burn down his barn." After the therapist discussed the possible consequences of such an action, John, at the request of the therapist, made a verbal promise not to burn down his father's barn. The therapist believed that John would keep his promise and did not disclose the threat to John's family or to other staff at the Counseling Service. During the night of June 27, 1979, John set fire to the barn located 130 feet from his parent's house. The barn was completely destroyed.

John's father brought a negligence suit against the Counseling Service claiming professional malpractice and alleging that the property loss resulted from failure to take reasonable steps to protect him from the threat posed by his son. The trial court dismissed the case with prejudice because it determined that under existing Vermont law there was no basis to impose a duty upon the Counseling Service to protect the father. The case was appealed to the Vermont Supreme Court.

In a 4-1 decision, the state Supreme Court reversed the lower court decision, holding that the mental health agency by and through its counselor-psychotherapist had a duty to warn the parents that their outpatient son had threatened to burn down their barn and that the failure of the mental health agency to disclose this threat constituted a breach of duty. This breach of duty was sufficient to impose liability. The case was sent back to the trial court for the entry of judgment against the Counseling Service.

In reaching this conclusion, the majority of the justices affirmed the principle that a mental health professional who knows or, based upon the standards of the mental health profession, should know that his or her patient poses a serious risk of danger to an identifiable victim has a duty to exercise reasonable care to protect him or her from that danger. The four justices rejected claims that the absence of control over outpatients, the limited ability of anyone to predict violent behavior or the centrality of confidentiality in mental health treatment should limit the liability of therapists in cases such as this. A key factor in the majority's conclusion was the factual record compiled by the trial court. Discussion of this and other aspects of the case will continue in next month's column.

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REFERENCE

1. Peck v The Counseling Service of Addison County, 499 A.2d. 422, 1985.

We know your time is valuable.

That's why we're asking you to take the time to watch a valuable 10-part series on Public Television this Fall entitled **"Managing our Miracles: Health Care in America."**

Produced by Columbia University Seminars on Media and Society, "Managing our Miracles: Health Care in America" will be broadcast on Connecticut Public Television on Tuesday evenings from 9-10 P.M. Each week, the series will bring together panels of nationally-known leaders and decision-makers to debate many of the medical, legal, and ethical problems which you, as a physician, confront every day. A distinguished moderator will lead the panelists through hypothetical case studies, presenting a balanced and thoughtful discussion of issues which can neither be simplistically answered nor safely ignored.

We urge you to watch "Managing our Miracles: Health Care in America." Not to hear easy answers, but to discover a way in which we all can work together to find workable solutions.

Programs may be viewed on Connecticut Public Television Channels 12, 24, 49, 53, 65 on Tuesday evenings at 9:00 P.M. Please check your local program guide for last-minute scheduling changes.

October 7: "Truth and Confidences." An exploration of the relationship between doctor and physician, moderated by Harvard Law School Professor Arthur R. Miller, and featuring panelists Supreme Court Justice Harry Blackmun; Dr. Willard Gaylin, President of the Hastings Center; philosopher Sissela Bok; Rhode Island Attorney General Arlene Violet; Dennis Campbell, Dean of the Duke University Divinity School.

October 7 (10 P.M.): **"Transplants: Second Chance at Life."** An examination of the harvesting and distribution of human organs, moderated by Yale University President Benno Schmidt and featuring panelists Dr. Michael DeBakey; Senator Albert Gore of Tennessee; Surgeon General C. Everett Koop; ABC Medical Correspondent George Strait; New England Journal of Medicine Editor Dr. Arnold Relman; nationally-syndicated columnist Ellen Goodman.

October 14: "The Human Heart Machine." A discussion of the risks and benefits of the artificial heart, moderated by Benno Schmidt and featuring panelists Dr. William DeVries; Dr. Robert Jarvik; Senator Albert Gore.

October 21: "Malpractice." A discussion of what malpractice and the malpractice crisis means to doctors and their patients, moderated by Harvard Law Professor Charles Nesson and featuring panelists Justice Harry Blackmun; Dr. James Todd, Vice President of the American Medical Association; Surgeon General C. Everett Koop; "Nightline" host Ted Koppel.

October 28: "AIDS: In Search of a Miracle." An examination of some of the vital questions presented by this frightening health crisis, moderated by Harvard Professor Arthur Miller and featuring panelists New York Mayor Ed Koch; Dr. Mathilde Krim, co-chair of the American Foundation for AIDS Research; Georgia Congressman Newt Gingrich; Dr. James Chin, Chief of Infectious Diseases at the California Department of Health; CBS Correspondent Susan Spencer.

November 4: "Technology Rocks the Cradle." A discussion of the issues surrounding pre-natal testing and the advances in neonatology, moderated by Columbia Law Professor Harold Edgar, and featuring panelists John Cardinal Krol; Surgeon General C. Everett Koop: CBS Correspondent Ed Bradley; Massachusetts Congressman Barney Frank.

November 11: "The Smoking Dilemma." A discussion about who's responsible for regulating smoking in public and whether or not tobacco advertising should be banned completely, moderated by Professor Charles Nesson and featuring panelists Surgeon General C. Everett Koop; R.J. Reynolds Tobacco Company Counsel John Strauch; California Congressman Henry Waxman; Eugene Patterson, Chairman of the St. Petersburg Times; Columnist Ellen Goodman.

November 18: "Battered Child, Battered Trust." A second examination of the patient/physician relationship, this time as it relates to its impact upon the growing number of abused children in our country, moderated by Professor Arthur Miller and featuring panelists Justice Harry Blackmun; Dr. William Gaylin of the Hastings Center; Dr. Arnold Relman of the New England Journal of Medicine; Philosopher Sissela Bok; Rhode Island Attorney General Arlene Violet.

November 25: "The Business of Medicine." A discussion of what the many changes in health care delivery may mean to someone who needs treatment, moderated by Columbia Law Professor Lewis Kaden and featuring panelists Joseph Califano, former Secretary of Health, Education and Welfare; California Congressman Henry Waxman; David Jones, Chairman of Humana Hospitals; Dr. Arnold Relman of the New England Journal of Medicine; Economist Lester Thurow; Pennsylvania Governor Dick Thornburgh.

December 2: "Final Choices." A discussion of health care for the elderly and the terminally ill, moderated by Benno Schmidt and featuring panelists Justice Harry Blackmun; Surgeon General C. Everett Koop; Colorado Governor Richard Lamm; ABC's Ted Koppel.

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Connecticut Medicine

The Journal of the Connecticut State Medical Society
160 St. Ronan Street, New Haven, CT 06511

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Editorials

Liver Transplantation

There were 602 liver transplants performed in the United States in 1985. The geographic distribution was quite uneven; a large share was done in Pittsburgh, none in New York City. Here in Connecticut Dr. Robert Schweizer and his colleagues at Hartford Hospital, after developing highly successful programs in kidney and heart transplantation, began transplanting livers in 1984. Yale also began a liver transplant program in that year. In this issue of *Connecticut Medicine*, the Hartford surgeons describe the background, indications, technique, and results of liver transplantation.

The surgical procedure is incredibly complex and difficult, and the procedure is further complicated by the very ill condition of patients with end-stage liver disease. Technological advances, such as the extracorporeal venous shunt and the red blood cell saver as well as the use of cyclosporine for immunosuppression, have helped make the procedure possible. The skilled liver transplantation team must spend many hours in the laboratory before attempting human transplantation. The logistics of donor liver procurement, preservation and transportation, as well as the performance of the five difficult anastomoses required, add to the complexity and expense of the procedure. Postoperative diagnostic procedures, laboratory tests, and medications add to the expense. The average cost of a liver transplant in this country is $130,000.

Many problems remain before liver transplantation can be considered a "routine" method of treatment for end-stage liver disease. These include:

1) Better methods for identifying protential recipients and establishing the optimal timing for the graft.

2) Improved methods for locating, procuring, and especially improved preservation methods for donor livers.

3) Further refinements of techniques such as methods to reduce blood loss due to portal hypertension.

4) Development of less toxic methods for immunosuppression. The drugs currently used contribute greatly to the expense, morbidity, and mortality of all organ transplantation procedures. Total lymphocyte irradiation or other techniques to induce host tolerance for grafted tissues and organs may be the way of the future in organ transplantation.

Despite the recent important advances in liver transplantation and the development of centers capable of performing this formidable procedure, one severe limitation to liver transplantation is that few cadaver organ donors are *liver* donors. The problem is usually not due to a paucity of people dying who could be liver donors, but the lack of awareness of the need for livers for transplantation and occasionally refusal, for unknown reasons, by next of kin to permit liver donation. Physicians and other health care workers could save the lives of many patients with end-stage liver disease simply by encouraging families to permit liver donation from suitable potential organ donors. In the past year at Hartford Hospital, three young people with acute liver failure died before a liver was made available for transplantation anywhere in the eastern United States.

Liver transplantation has certainly come a long way in a relatively short period of time. Those involved in developing this complex service for patients in Connecticut deserve congratulations.

Robert S. Rosson, M.D.

Chief of Gastroenterology
Hartford Hospital;
Associate Clinical Professor of Medicine
University of Connecticut School of Medicine

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself responsible for statements made by any contributor.

Editorial

"When Doctors Disagree"

Fifty years is hardly a venerable age, but it is a respectable one in the history of medical journalism; *Connecticut Medicine* has settled into its ecological niche after half a century and might rest secure except that the ecology, as ecologies always do, is changing. How fast and how profoundly is anyone's guess. We are too close in time to know, and since we are part of the change our relative positions make judgment difficult and agreement unlikely.

At the August meeting of the Editorial Board there was a generally expressed opinion that the Journal need not change much, that its balance was about right and its personality suited to Connecticut medicine. At the same time several members of the Board urged that the present controversies in and around medicine should find expression in the Journal; that the economic, political, cultural, and organizational changes taking place are much too critical and certainly far too interesting to ignore. To extend the allusion to the first Hippocratic aphorism, not only is judgment difficult, but the "opportunity fugitive; experience delusive;" nevertheless we should try to capture the controversies in these pages. This may be done most safely by description, analysis, explanation, and from time to time by reasoned debate. In most instances internecine controversy ought to be editorially shunned, except in Letters to the Editor, always welcome, and which, more than anything else, capture those fleeting occasions which it is the Journal's task to record.

Some have suggested that we are living in a time of paradigmatic change of the kind described in Thomas Kuhn's "The Structure of Scientific Revolutions." Something like that was implied recently by the former president of Blue Cross-Blue Shield, Walter J. McNerney, when he described medicine as passing from "its ecclesiastical phase to a commercial phase."

Perhaps, but paradigm shifts in science are irreversible; no one will take up the phlogiston theory again, and the Ptolemaic universe is only a relic. Medicine has been idealistic and pragmatic, a trade and a profession, ecclesiastic and commercial by turns for as long as we have records of doctors and patients. Rather than a paradigm shift, we may be passing through another historic cycle in which change is certain but the outcome unpredictable; in any event historical change should be managed, and *Connecticut Medicine* should be able to assist in that effort and to record its progress.

There are risks in coming too close to day by day political issues, especially those in which the house of medicine may be divided, as between the "for-profit" and the "not-for-profit" medical institutions; or those which are local, and no outsider could understand the real issues, as between a hospital and striking professional workers. Nevertheless it is in these particular occasions that the values of our profession may discover their sharpest definition. In almost every encounter there is more than self-interest at stake, and in science there are generally no irresolvable disputes over conclusions to be drawn from sound data. "Who shall decide, when Doctors disagree?" asked Alexander Pope in "Moral Essays," implying that disagreements were sharpest when moral principles were at issue.

Whether medicine indeed is in the midst of a paradigm change, or whether it is being swept along by the economics of the late 20th century, or whether the changes are reflections of the larger society changing its moods or its fashions, it is the task of medical journalism to record the events and to help us to understand their significance.

Robert U. Massey, M.D.,
Editor

Financing Care for the Elderly

Every physician who cares for older patients has become painfully aware of the gradual but persistent tightening up of the expenditure of Medicare funds. Nursing homes and home health agencies are faced with either denying services or providing them without reimbursement at a time when their costs are rising and their older patients are sicker. Several years ago as our medicine watchers foresaw the fiscal troubles increasing they predicted that it would be the children and the elderly who would suffer.

Elsewhere in this issue we have published the complete report of the AMA Board of Trustees' "Proposal for Financing Health Care of the Elderly," which was prepared for the House of Delegates in June 1986. It deserves careful reading, not only by physicians and others concerned with the care of the elderly, but by all of us, including our legislators and their staffs. Old age has become increasingly difficult to avoid; barring catastrophe, more and more of us will be celebrating not only the beginning of the eighth decade of our lives, but the ninth and even the tenth. Most of those celebrations will be in good health, but the inevitable disabilities will come to many, frequently wiping out a lifetime of savings and imposing intolerable burdens on aging children and young grandchildren.

There are ways of lightening that burden and our resourceful society must discover them. The AMA proposal is a sound one and should command thoughtful consideration; it seeks a way to solve a problem important as any which we as physicians with our whole society now face.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

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Public Affairs

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Scientific Activities

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Government Relations

CALL

SEMI-ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1986 Semi-Annual Meeting of the House of Delegates will be held at the Ramada Inn, Meriden commencing at 12:30 P.M. on Wednesday, November 19.

Joseph C. Czarsty, M.D., President
Lawrence B. Ahrens, M.D., Speaker of the House
Annemarie Welch, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides:

Resolutions may be introduced by any Active or Life Member or student members or postgraduate physician members of the Society, in compliance with the following provisions:

a. *All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*

b. *Component county associations or the student members or postgraduate physician members, whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.*

c. *Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.*

d. *Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

PROPOSED AMENDMENT TO THE BYLAWS

The following proposed amendment to the Bylaws was presented to the House of Delegates on May 7, 1986 and was tabled for consideration and action at the next regular meeting of the House of Delegates.

In accordance with the Bylaws, this amendment is being published in Connecticut Medicine "on one or more occasions prior to the next meeting....at which meeting the amendment shall be taken off the table and acted upon by the House of Delegates.

SUBJECT: DUES FOR NEW MEMBERS

OBJECTIVE: To reduce the dues of all new members who are elected in the spring to one-half the annual dues.

PROPOSED AMENDMENT: ARTICLE XII—DUES

Section 1. Prescription—(Add words in capitals)

Par. 1—Annual dues for Active Members shall be prescribed for the ensuing fiscal year in an amount recommended by the Council and approved by the House of Delegates and shall be an equal per capita assessment upon each Active Member except that physicians who become Active Members during the SPRING WILL BE ASSESSED ONE-HALF OF THE ANNUAL DUES FOR THAT FISCAL YEAR AND PHYSICIANS WHO BECOME ACTIVE MEMBERS DURING the latter half of a fiscal year will be assessed one-quarter of the annual dues for that fiscal year.

Council Meeting

July 23, 1986

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice Chairman Dr. M.S. Eslami were: Drs. Ahamed, Beck, Bobruff, Czarsty, Fox, Freedman, Friedberg, James, Kamens, Orphanos, Ragusa, Sadowski, Sullivan, Sweet, Waldron, Wetstone, Zanker and Zlotsky.

Also present: Drs. Hinz and Whalen. Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Sullivan, Mr. Staples, Ms. Marcus, Mr. Tomat, Mr. Freberg, Mr. Coffey.

Absent were: Drs. Abbot, Ahrens, Bonner, Canzonetti, Dardick, Finn, McDonnell, O'Brien, Petrie, Reyelt, Robbins, Rose, Schwartz, Villa and Welch.

Approval of Minutes

The minutes of the June 5th meeting were approved as distributed.

Reports from Physicians Serving on State and Federal Agencies

Dr. Friedberg reported his concern that information being utilized for a relative value study at Harvard University did not accurately reflect the true nature of physicians' practices. He mentioned that the Department of Health and Human Services was intent on using the results of this study to establish fee schedules, and that the AMA was closely monitoring the study's progress.

Dr. Eslami also mentioned that federal funding will end for all Health Systems' Agencies on October 1, 1986, and that only the Hartford County-based Agency would continue with private funding support.

Report of the President

Dr. Czarsty reported that the CSMS-IPA had more than 2300 enrolled members, making it the largest IPA in Connecticut. He also mentioned that the Steering Committee had approved the IPA Bylaws, which were before the Council for consideration and that Dr. Whalen would continue the discussion concerning the CSMS IPA-HMO later in the agenda.

Report of the Executive Director

Mr. Norbeck reported on the following items:

(a) COMPAC—A telethon was planned to increase membership.

(b) IPA-HMO—The IPA response has been overwhelming and the project is proceeding on schedule.

(c) Leadership Conference—The Second Annual Leadership Conference is scheduled for Saturday, September 6, at the Sheraton Hotel in Waterbury. Planning for the program format and speakers is underway.

(d) Democratic Platform—The Connecticut Democratic Party's platform was successfully amended to include a recommendation for a Senior Courtesy Card program as an alternative to mandatory assignment legislation.

(e) Ad Hoc Committee on Medicare Assignment—Dr. Czarsty has been appointed to a legislative task force investigating the issue of medicare assignment.

Report on AMA Meeting, Chicago, June 15-19, 1986

An attachment entitled "Highlights of the AMA Annual Meeting," prepared by Stewart Petrie, M.D., and a document prepared by the AMA entitled "Delegates Report" were distributed at the meeting and were received as information.

Dr. Kamens mentioned that Dr. Van Syckle should be congratulated for his leadership role as a reference committee chairman at the AMA meeting. Dr. Kamens also discussed his concern about legislative proposals under consideration by the AMA that would protect physicians from adverse decisions by Peer Review Organizations.

Dr. Freedman reported that the AMA intended to improve its handling of inquiries concerning impaired physicians by thoroughly reviewing its membership files and guaranteeing a one week turnaround on requests for information. He also reported that the Council on Medical Education was urging that residency programs provide malpractice insurance for residents with tail coverage which would include acts occurring during residency but which may come to light after completion of residency training. There was a gap found between the coverage a resident had in the hospital and the insurance he would obtain in practice.

Dr. Freedman also brought to the attention of the Council an AMA report entitled "Proposal for Financing Health Care of The Elderly" which describes a new approach developed by the Council on Medical Service and Council on Legislation, for financing health care of the elderly. It was VOTED to publish the report in *Connecticut Medicine,* for the information of the membership.

IPA-HMO Report

Dr. Whalen reported that the Steering Committee had issued Requests for Proposals (RFPs) to the HMOs in Connecticut, as well as to a number of management/development firms around the country. The Steering Committee had voted to recommend to the Council a contract be approved that would authorize Attorney Barry Scheur to set up and direct a development team for the IPA-HMO. Three subcommittees were also underway covering Credentials, HMO Bylaws, and Quality Assurance-Utilization Review.

The IPA Bylaws, which had been approved by the Steering Committee on July 7, copies of which had been distributed to the Council with the agenda, were discussed and one amendment was proposed. It was VOTED to approve the following amendment to Article VI, entitled, County Chapters: (Amendment underlined)

> "THERE SHALL BE ESTABLISHED BY CSMS-IPA MEMBERS IN EACH COUNTY IN THE STATE OF CONNECTICUT A COUNTY CHAPTER OF IPA COMPRISED OF ALL IPA MEMBERS IN THAT COUNTY, WHO ARE

ALSO MEMBERS IN GOOD STANDING OF THEIR RESPECTIVE COUNTY MEDICAL SOCIETIES....."

It was VOTED to unanimously approve the Bylaws of the CSMS IPA, Inc., as amended.

Attorney Barry Scheur discussed his proposal to form a management team under the direction of a development subsidiary formed by his new law firm of LeBoeuf, Lamb, Leiby and MacRae, Inc., in New York. Mr. Scheur recommended that CSMS retain outside counsel to negotiate the agreement with his development firm.

Following discussion of Mr. Scheur's proposal, the Council VOTED to approve his proposal subject to approval of outside counsel.

Committee on Physician Health

The following documents, which had been approved by the CSMS Committee on Physician Health, had been distributed to the Council for consideration:

(1) Procedures Governing the Impaired Physician Program of the Committee on Physician Health.

(2) Protocol Governing Participation of Established Medical Organizations in the Implementation of Public Act 84-148.

It was VOTED to approve the documents as the basis of negotiations with the Department of Health Services.

Report Re: Medicare Part B Litigation

Dr. Friedberg reported on his discussions with a representative from HCFA concerning the retrospective audits performed on nursing home charges. He mentioned that the HCFA representative had no suggestions to make concerning a resolution of this problem. He felt that legal action was not a recourse open to CSMS.

Attorneys Linda Randall and Jeannette Schreiber from Wiggin and Dana discussed their assessment of CSMS's chances for succeeding in a lawsuit against HCFA. They mentioned that subsequent to a recent Supreme Court decision, there is now a right to judicial review of the *methods* by which benefits are determined, but no review available for the *amount* of the benefits. While CSMS might succeed on the grounds of a right to a hearing, or that monthly visits should be presumed to be medically necessary, the likelihood of winning was less than 50%. With the carrier changing from Connecticut General to Travelers, winning the case would not be as effective against the former carrier.

It was VOTED to table any further legal action until such time as Travelers' policies become evident.

Attorney Randall also mentioned that the CSMS suit against the Board of Examiners for Podiatrists was still pending.

International Association of Cancer Registries

Received as information was a letter thanking CSMS for its contribution of $2,000.00 to help defray the cost of a meeting of the subject group in Hartford. The meeting was a huge success and contributions exceeded their expenses, therefore a refund check in proportion to contributions made were sent back to contributors. CSMS received a check for $1,080.93.

Life Members

It was VOTED to receive as information the following names of Life Members:

Michael D. Albis, M.D., 60 Edwards St., East Haven (NH)
Dorothy W. Brockway, M.D., 21 Old Mill Rd., Woodbridge (NH)
Arnold W. Forrest, M.D., 196 Danbury Rd., Wilton (F)
Harvey W. Kaetz, M.D., 60 Temple Street, New Haven (NH)
Paul T.C. Lin, M.D., 121 Wakelee Avenue, Ansonia (NH)
John E. Standard, M.D., 1211 W. Main Street, Waterbury (NH)

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on July 23, 1986. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the society.*

Mark Your Calendar

CONNECTICUT STATE MEDICAL SOCIETY
SEMI-ANNUAL MEETING - HOUSE OF DELEGATES

Wednesday, November 19, 1986
RAMADA INN
MERIDEN, CT

******

CONNECTICUT STATE MEDICAL SOCIETY
195th ANNUAL MEETING

******

HOUSE OF DELEGATES
Wednesday, May 6, 1987

ANNUAL SCIENTIFIC ASSEMBLY
OF THE SOCIETY
Thursday, May 7, 1987

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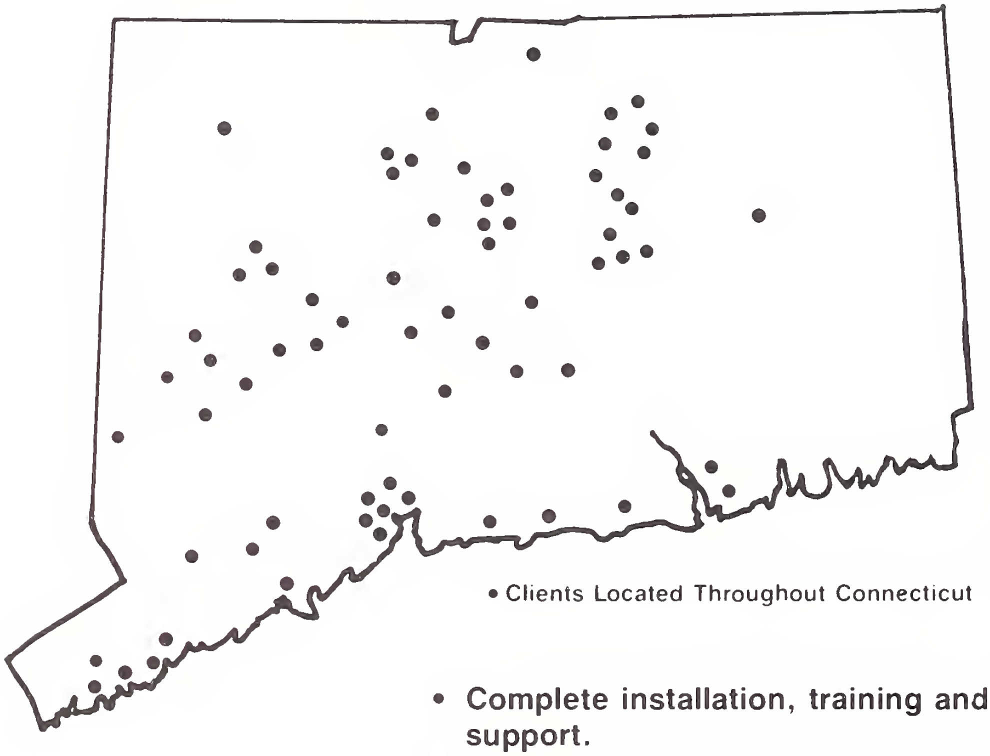

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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Excellent full time position available at St. Mary's Hospital in Connecticut for a talented physician with experience in Emergency Medicine. There is excellent medical staff support in all specialties and we have an outstanding hospital-based EMS System with paramedic staffing. Our location in Waterbury combines the utmost in family living with proximity to the cultural advantages of Hartford and New Haven. Excellent compensation and benefits accompany this opening. Please send CV to Louis Gottlieb, M.D., Director, Emergency Medical Services, St. Mary's Hospital, 56 Franklin Street, Waterbury, CT 06702, or call (203) 574-6010.

EMERGENCY MEDICINE/INTERNAL MEDICINE

Urgent Care Physician. Emergency Medicine or Internal Medicine physician needed for free-standing walk-in treatment center in central Connecticut. Board certified preferred. Benefits and competitive salary. Send CV to: A.M.G., P.O. Box 937, Avon, CT 06001.

FAMILY PRACTICE

Part time family practitioner needed for physician's office. Please call 248-8142.

For Sale. Family practice, no Pediatrics. Excellent location in southern Fairfield County, CT. Good opportunity for Spanish speaking physician. Please send replies to CSMS, c/o FP/QQ.

Young, expanding group practice in Western Connecticut seeking BC/BE family practitioner to join family practice in existing office. Highly desirable area. No OB. CV to: Brookfield Health Associates, P.C., 940 Federal Road, Brookfield, CT 06804.

Family practitioner needed to join fast growing two physician practice in Danbury-Waterbury area. Please forward C.V. to, Director, Family Health Care Center, 141 North Main St., Southbury, CT 06488. (203) 264-8884.

INTERNAL MEDICINE

Practice For Sale. Internal Medicine and Cardiology practice immediately available. High quality, well-established practice in New Haven, CT. Fully equipped, staffed office. Scheduled appointments awaiting energetic BC/BE physician. Opposite major hospital. (203) 624-5037.

General internal medicine specialist wanted for 1987 to join four established solo practitioners in a rural setting who are merging and forming an internal medicine group practice. If interested, please send particulars and CV to CSMS, c/o IM/CX.

The Northeast Permanente Medical Group, P.C., the Medical Group for the Hartford Connecticut area of the Kaiser Permanente Medical Care Program's Northeast Region, is seeking BC/BE general internists for 1986 and 1987. The Hartford area serves over 25,000 members from ambulatory care facilities in East Hartford, Farmington, and Windsor. The Medical Group is a multi-specialty prepaid practice organized as a professional corporation. Applicants should have a strong interest in primary care. Salary and benefits are highly competitive. All inquiries and resumes should be addressed to: Physician Placement Dept., Northeast Permanente Medical Group, P.C., 60 Washington St., Suite 401, Hartford, CT 06106.

Internist, BC/BE, with pulmonary subspecialty, for busy internal medicine group in Connecticut. Send CV to CSMS, c/o IM/JE.

OBSTETRICS/GYNECOLOGY

Southwest Connecticut. BC/BE Obstetrician/Gynecologist. Excellent opportunity in well-established progressive practice. Ultrasound; colposcopy; fetal monitoring. Office across the street from hospital. Need fourth partner. Send CV to CSMS, c/o OB/AZ.

FOR SALE. Ob/Gyn practice with office close to modern hospital. Northwest Connecticut, country living. University center easy travel. Retiring. Gross $300,000. Will introduce during transition. Write CSMS, c/o OB/CC.

Young solo OB/GYN, Board Certified seeks BE/BC Associate for busy private practice in a beautiful resort community in southern Connecticut. Excellent opportunities for higher education, water recreation, shopping. Easy access to New York City, Boston, Hartford, Cape Cod and skiing. Very stable economy with low unemployment. Please forward CV to: Stanley P. Solinsky, M.D., 449 Montauk Ave., New London, CT 06320 or call (203) 447-2377.

Central Connecticut. Full service community hospital wishes to attract solo practitioner, BC/BE, for private practice. Growing population base; central location. Excellent opportunity for affiliation with a progressive Medical and Administrative staff. Incentive program available to qualified applicant. Send CV to CSMS, c/o OB/LL.

OTOLARYNGOLOGY

Central Connecticut. Full service community hospital wishes to attract solo practitioner, BC/BE, for private practice. Growing population base; central location. Excellent opportunity for affiliation with a progressive Medical and Administrative staff. Incentive program available to qualified applicant. Send CV to CSMS, c/o OTO/JK.

PART TIME

U.S. Department of Defense needs physicians to do pre-enlistment physicals. Suitable for semi-retired/retired physician and could amount to two or three mornings a week from 8:00 a.m. to 11:00 a.m. Contact Major Mark R. Lehrman, (203) 773-2359.

PART TIME—Continued

Hospice Physician, part-time day position with some on call responsibilities available on the medical staff of the nation's first hospice. The Connecticut Hospice is a JCAH accredited hospital with a 44-bed in-patient facility and a hospice based home care program of 50 patients. Excellent opportunity for a physician interested in palliative care. Connecticut license required. Board certification preferred. Please send C.V. to John M. Stober, Director of Human Resources, The Connecticut Hospice, Inc., 61 Burban Drive, Branford, CT 06405. E.O.E.

PEDIATRICS

Medical Director—Pediatrician 12-20 hours. Residential school for multi-handicapped children to age 21. Infirmary, nursing staff, consultants. Need pediatrician for direct medical care and overall supervision of health needs. Contact Anne Lasser, (203) 242-2274.

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Intraoperative Arterial Balloon Angioplasty

MAGRUDER C. DONALDSON, M.D. AND JOEL M. ROSENBERG, M.D.

ABSTRACT– Arterial balloon angioplasty was performed on twelve arteries during operation on eleven patients over a three year period. Important indications were correction of underlying arterial stenosis after catheter thromboembolectomy and correction of unexpected hemodynamically significant inflow disease at the time of femorodistal reconstruction. A simple technique was executed without complication. Excellent immediate results were obtained, and arterial patency was maintained over a 1-30 month follow-up period. Because balloon angioplasty may occasionally be useful in the operating room, surgeons should consider adding it to their repertoire.

Percutaneous transluminal angioplasty (PTA) was first reported in 1964 by Dotter and Judkins[1] and popularized by Gruntzig.[2] It has been applied in a wide variety of situations, but is most successful in patients with isolated short segment stenosis in large proximal arteries. It is possible to dilate such vessels in more than 90% of instances, and patency ranges from 60-80% of femoral arteries to 70-92% of iliac arteries at 3 years.[3-8] Complication rates of 6-15% are reported, consisting largely of groin hematoma, distal embolization, early thrombosis and rarely arterial rupture at the site of angioplasty. Though longterm efficacy is not as good as bypass surgery,[9] the brief hospital stay and recovery periods usually possible together with low rates of severe morbidity make the procedure useful in palliating atherosclerotic arterial disease.

It is usually most advantageous to perform PTA in the radiology suite, often at the same time as diagnostic arteriography. On twelve occasions over a three year period in our experience, however, angioplasty was carried out in conjunction with a vascular surgical procedure in the operating room.

Materials and Methods

After surgical exposure of the common femoral artery and systemic heparinization, baseline pressure was measured by needle puncture and compared to simultaneous arm pressure to establish the presence and degree of pressure gradient in the proximal iliac system. A flexible-tipped guide wire was introduced into the femoral artery using Seldinger technique in nine cases and advanced through the stenotic lesion under C-arm fluoroscopic control. On three occasions, the femoral artery was opened surgically for wire introduction. A balloon angioplasty catheter (Meditech, Watertown, Mass.) of appropriate size was selected by measurement of the diameter of the target artery on the preoperative arteriogram, and introduced over the guidewire through the stenotic lesion. Balloon preparation and arterial dilation were performed as described in the literature.[4-8] In most cases angiographic contrast medium (Renografin 60) was flushed by hand through the catheter to obtain fluoroscopic visualization of the arterial anatomy before and after angioplasty. Frequent arterial pressure tracings and measurements could be obtained through the open end of the catheter at any position within the artery. Before withdrawal of the catheter, pressures were measured below proximal treatment segments to confirm correction of the pre-treatment pressure gradient. If the femoral artery had been opened, vigorous flushing was possible after catheter removal. Adjunctive procedures such as femorofemoral or femoropopliteal grafts were performed after angioplasty had been successfully completed. Arterial dilation was performed by the surgical team in all but one instance in which a radiologist scrubbed, and the angioplasty portion of the operation never took longer than twenty minutes.

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Reprint requests to: Department of Surgery, University of Connecticut Health Center, 263 Farmington Ave., Farmington, CT 06032 (Dr. Donaldson).

Presented at the Annual V A Vascular Meeting at Castle Point, V A Medical Center, October, 1985.

Results

Eleven patients underwent intraoperative balloon angioplasty, one of whom had two arteries treated at the same operation. Of this total of twelve procedures, nine involved isolated common or external iliac stenoses and three were for superficial femoral stenoses (Table 1). In four instances, lesions were dilated in common iliac arteries which served as donor vessels for femorofemoral bypass grafts performed at the same sitting. Similarly, two common iliac arteries were treated just prior to femoropopliteal and femorotibial bypass using autologous vein. One patient was taken to the operating room eighteen months following aortoiliac bifurcation grafting when one limb of his graft occluded. Preoperative arteriography demonstrated a stenotic area in the external iliac artery just below the anastomosis of the patent limb (Figure 1). A thrombectomy was performed, and a similar lesion on the occluded side was revealed by fluoroscopy. Balloon angioplasty restored the lumen to a more normal caliber and the patent but stenotic artery on the opposite side was treated at the same time. A single common iliac stenosis was treated in a patient with unilateral disease with a small femoral cutdown under local anesthesia early in the series.

Table 1
INTRAOPERATIVE BALLOON ANGIOPLASTIES

External iliac artery after iliac thrombectomy	2
Common iliac artery before femoropopliteal bypass	2
Common iliac artery before femorofemoral bypass	4
Primary common iliac artery	1
Superficial femoral artery after femorofemoral bypass	1
Superficial femoral artery with femoral thrombectomy	1
Superficial femoral artery before below knee amputation	1

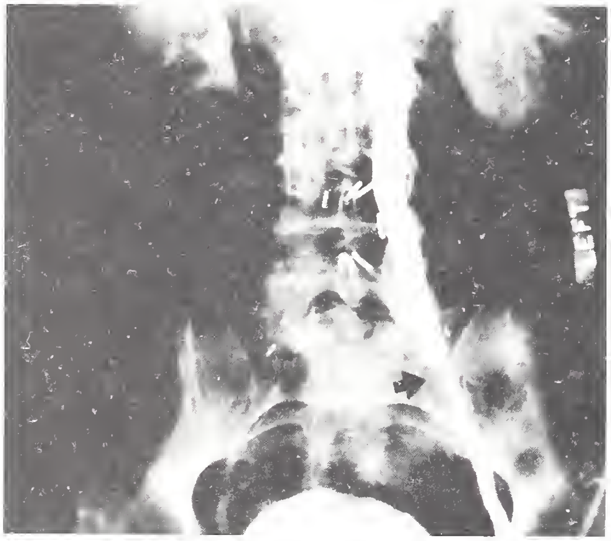

Figure 1

Preoperative arteriogram of a patient who presented with acute thrombosis of the right limb of an aortoiliac bifurcation graft, demonstrating stenosis of the external iliac artery just below the anastomosis on the patent left side (arrow). Following thrombectomy under local anesthesia, a similar lesion was identified underlying the occluded limb using angiographic dye and fluoroscopy. Both stenoses were successfully dilated intraoperatively and remained patent for 24 months.

One of the femoral angioplasties was performed in a tightly stenotic superficial femoral artery after a femorofemoral bypass. Another lesion was treated in a patient who presented with acute foot ischemia and was found to have ipsilateral iliac stenosis and superficial femoral occlusion by preoperative arteriography. The iliac lesion was successfully dilated percutaneously in the radiology suite with minimal hemodynamic improvement in the foot, so the patient was taken to surgery where a fresh thrombus was retrieved from the superficial femoral artery. Operative arteriography demonstrated a tight stenosis at the adductor canal, which was dilated by balloon (Figure 2). Finally, a single patient early in the series with an unsalvageable foot and diffuse stenoses of the superficial femoral artery was taken to surgery for a below knee amputation. Because flow to that level was judged marginal, simultaneous femoral balloon angioplasty was undertaken, with sufficient improvement in perfusion at the amputation site to allow healing.

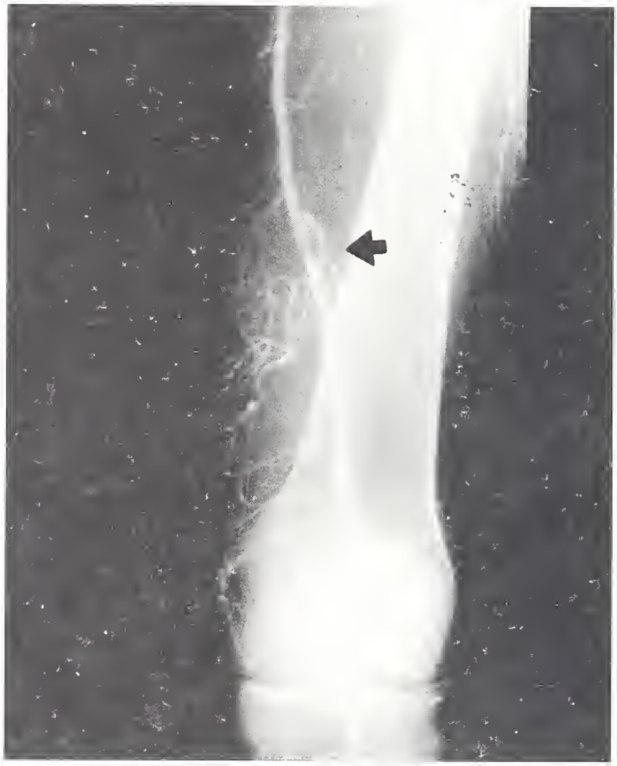

Figure 2

Operative arteriogram obtained from a patient following thrombectomy after acute occlusion of the superficial femoral artery. The stenosis at the adductor canal (arrow) was dilated intraoperatively and remains patent at 15 months.

There were no balloon angioplasty failures, and no operative complications or mortality within thirty days of surgery. In a follow-up period ranging from one to 30 months (mean 9.7 months), there was only one occlusion of a dilated segment. This occurred on one side 24 months after treatment in the patient who had bilateral external iliac angioplasties following aortoiliac grafting.

Discussion

In many institutions, cardiovascular radiologists have developed sufficient expertise to provide angioplasty at the same sitting as diagnostic arteriography. With noninvasive vascular laboratory data, direct arterial pressure monitoring in the radiology suite, and vascular surgical support, the presence of hemodynamically significant lesions and the propriety of correcting them can be determined. Corrective balloon angioplasty using optimal imaging and completion angiography can be performed either as definitive therapy or prior to planned bypass of associated occlusive disease. During the three year period covered by this series, a total of 73 balloon angioplasties were performed in the radiology suite at our two institutions. In this series of twelve balloon angioplasties, seven were performed early in our experience on iliac lesions which, with preoperative pressure measurements, would now most often be detected and treated in the radiology suite.

There are selected circumstances in which patients may be better served by using balloon angioplasty as an intraoperative adjunct to a vascular surgical procedure. The best example is when thrombectomy after acute arterial or graft occlusion reveals an underlying causative stenosis. Three of the twelve arteries treated in our series fit into this category. Rather than performing a corrective bypass, many surgeons might consider angioplasty in such situations, particularly in the case of a single stenotic lesion located in an iliac artery. Simultaneous intraoperative angioplasty served well in our experience, and may be preferable to closing the wound and returning to the radiology department for a separate procedure.

Occasionally, lesions appear on preoperative arteriography to be less than hemodynamically significant, but turn out to be important when tested with arterial pressure measurement at the time of surgery. Assurance of adequate inflow is crucial when femorofemoral or femoropopliteal bypass is planned below an iliac artery with some disease evident on preoperative Xray. Testing such arteries under conditions of decreased peripheral resistance, using intra-arterial papaverine injection or reactive hyperemia has been shown to be an effective means of predicting adequacy of flow through the donor artery[10] after adding such grafts. In our series, six patients were found to have marginal or inadequate donor iliac arteries with reduced resting pressures below isolated lesions. Though often detected and treated preoperatively, these lesions can be easily and conveniently managed by intraoperative balloon angioplasty.

Others have also found that a small proportion of patients appear to benefit from intraoperative angioplasty.[11-13] In general, the circumstances in these reports were similar to those in ours, where unexpected findings made it logical and convenient to proceed with balloon angioplasty at the same sitting as surgery. Fogarty et al[14] developed a special balloon which is extruded from a catheter through arterial lesions without preliminary placement of a guidewire past the lesion. The potential advantages of this technique are that a certain number of intimal injuries due to guidewire passage might be avoided, axial forces along the plaque during passage of the balloon are minimal, and the procedure can usually be performed safely without Xray visualization. Though this approach to operative angioplasty appears to hold promise, data on results in large series of patients is not yet available.

In many centers, the need for angioplasty can most often be ascertained before surgery, and the facilities are available to perform balloon angioplasty when indicated preoperatively by a percutaneous route. There are unusual circumstances, however, when intraoperative angioplasty in conjunction with arterial surgery may be advantageous. For this reason, familiarity with the technique should be encouraged among vascular surgeons.

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Ambulatory Alcohol Detoxification: An Alternative

MARK L. KRAUS, M.D., SAM R. SEGAL, M.A., C.A.C., VINCENZO SANGUINETI, M.D.,
MARIE JOHNSTON, R.N., C.A.C., AND CAROL GENOVA, R.N.

Introduction

St. Mary's Hospital is a 347 bed acute care general hospital located in Waterbury, Connecticut, serving a population of approximately 250,000. Joseph Center, a component of the Hospital's Department of Psychiatry, provides a comprehensive alcohol rehabilitation program which was expanded to include an Ambulatory Alcoholism Acute Treatment Unit (ATU) in January, 1985.

The ATU is designed to serve patients suffering mild to moderate symptoms of the alcohol withdrawal syndrome (AWS) while retaining the capacity to admit patients with more intense symptoms or vital signs to either a medical or psychiatric in-patient unit.

Program History and Philosophy

Joseph Center has been guided by the philosophy that alcoholism is a chronic and progressive illness affecting the individual and significant other(s) in his or her life in the physical, emotional, and social spheres. A further belief is that this disease can be arrested with appropriate treatment and involvement on a long-term basis with self-help groups.

The program's treatment efforts focus on the psychological, social, and physical aspects of the disease, and the orientation is toward assertive early intervention in the illness which addresses recognition of the agent (alcohol), and host (individual alcoholic), and the environment, including the family system and the employer. This intervention should be multidisciplinary in nature in order to apply the highest level of skills of each practitioner to the rehabilitation process.

Ambulatory alcohol detoxification occupies a valid position in the treatment strategy for an individual recovering from alcoholism. In applying the concept of ambulatory alcohol detoxification we express concern for a) who will be candidates for admission and b) if these patients can be managed medically as out-patients.

The AWS is in part a hyperadrenergic state. The worst scenario of this state is delirium tremens (DT's). DT's still has a high morbidity and mortality,[1] and patients in the DT's belong in an ICU setting. Patients who are in moderate to severe AWS should also be admitted to the hospital. The problem that exists in application of these principles of treatment is the definition and diagnosis of the stages of AWS. Attempts to stage AWS have been made but no uniformity exists to give staging world-wide acceptance.

The absence of a reliable staging system requires that unstable vital signs (temperature, pulse rate, blood pressure, respiratory rate), clinical signs (tremor, seizure, level of consciousness), and behavioral signs (anxiety, agitation, hallucination) will all have to be evaluated by the physician in order to make a clinical decision regarding the patient's disposition.

Patients who have metabolic, neurologic, cardiac, or gastrointestinal complications of alcoholism, or who have severe infectious disease, or who have co-morbid illnesses that would be compounded or further compromised by the hyperadrenergic state of alcohol withdrawal, should most likely be admitted for in-patient treatment and management of their alcoholism.

Our review of recent ambulatory detoxification studies leads us to the following conclusions: 1) when chosen according to carefully specified clinical criteria fewer than 10% of the alcoholics required in-patient detoxification; 2) selected patients followed in an out-patient setting had successful detoxification experiences without serious medical complications.[2,3]

Dimensions of the Problem

The National Institute on Alcoholism and Alcohol Abuse reported in 1982 that an estimated 14.7 million

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Americans suffer from alcoholism or problem drinking, and their numbers are increasing by nearly half a million people per year.[4,5]

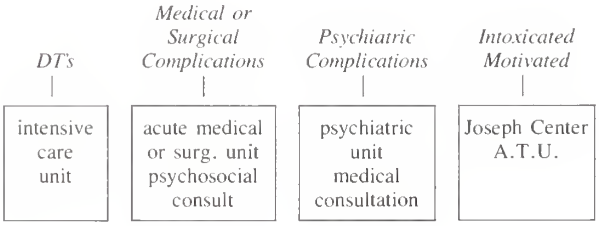
Alcoholism is commonly listed as the third or fourth leading cause of death in America; accounting for more than 127,000 premature deaths per year.[6-8] Each day, 71 people are killed and 2,000 people are injured in alcohol-related accidents.[9] Up to 68% of the people who drown, 50% of those who die in falling accidents, and 50% of those killed in fires had been drinking.[10]

Clearly, alcoholism is a public health problem of major proportions with extremely high costs for the patient, his or her family, employer, and for society in general. The National Center for Health Statistics, in a 1981 study of health costs, figured that when direct and indirect costs were totaled—alcoholism is second—at 43.2 billion dollars—only to heart disease, in terms of the economic burden placed on society.[11]

Medical Protocol of Ambulatory Alcoholism Acute Treatment Unit (ATU)

All alcoholic patients seeking help for their disease, who are free of opiate dependence and 18 years of age or older, can either present themselves to our Emergency Room or to their private physician, for voluntary admission to the ATU. See Table 1.

Table 1
ALCOHOLIC, 18 YEARS OLD. NO OPIATES EVALUATION BY PERSONAL PHYSICIAN OR EMERGENCY ROOM PHYSICIAN


DT's
intensive care unit
Medical or Surgical Complications
acute medical or surg. unit psychosocial consult
Psychiatric Complications
psychiatric unit medical consultation
Intoxicated Motivated
Joseph Center A.T.U.

The alcoholic patient will be screened medically by a physician and psychosocially by an alcohol counselor in the hospital Emergency Department. If patients are medically fit, showing only mild to moderate signs of the AWS and without major psychosocial problems, they are referred to the ATU. However, if the alcoholic patient who presents to the Emergency Department has medical problems, and/or is found to be in moderate to severe alcohol withdrawal, and/or has sufficient acute psychopathology to warrant in-patient treatment, the patient is admitted to the hospital as an in-patient.

Patients who go to their private physician's office seeking help for their alcoholism may be referred directly to the ATU after being screened by their doctor and found to be medically stable. If, however, the patient is found to have medical problems, and/or medical complications of alcoholism, and/or is found to be in moderate or severe AWS, then the patient is referred to St. Mary's Hospital Emergency Department for further assessment.

Patients who are admitted to the hospital as in-patients for treatment of their medical illnesses, and/or moderate to severe AWS, and/or complex psychosocial problems, are stabilized medically and psychosocially by physicians and alcohol counselors. A history and physical examination is performed, appropriate laboratory tests are ordered, x-rays are obtained, problems are defined and indicated treatment initiated to stabilize the patient. Once stabilized, these patients will concurrently participate in the psychosocial aspects of the ATU such as group counseling and education. Once discharged from the hospital they will be followed either in the ATU or referred for appropriate continuing care. Patients admitted to the hospital for alcohol detoxification or related problems are involved not only in resolving the collateral pathologies but also in initiating treatment for their underlying problem, alcoholism.

Alcoholic patients who are acceptable to the ATU are admitted to the program. A complete medical history and physical examination is performed upon their admission including the development of a baseline Alcohol Withdrawal Syndrome—Symptom Evaluation Score (AWS-SES) adapted from Knott, et al.[12,13] The AWS-SES is the principle measure of therapeutic efficacy of the alcoholic's clinical response. The index consists of nine signs and symptoms organized into 3 main categories: vital signs (temperature, heart rate, blood pressure); clinical signs (tremor, seizure, level of consciousness); and behavioral signs (anxiety, agitation, hallucination). Each member of a category is assigned a weight (see Table 2).[12] Application of this index allows patients to be assigned a score based on their worst level of function during the previous 24 hours. A score of '0' is the best—'27' the worst.

Patients admitted to the ATU are seen daily by the Detox Team—an M.D. and an R.N./Counselor. Appropriate laboratory, chest roentgenography and electrocardiogram are obtained. All patients participating in the ATU are medically managed for the AWS by the following therapy, which is standard for Joseph Center and consists of: 1) a daily medical clinical evaluation; 2) alcohol breath analysis; 3) vitamin supplementation; 4) sedation on a p.r.n. basis with a benzodiazepine—Oxazepam; 5) fluids. Medicines given to the patient are dispensed after lengthy instructions by the R.N./Counselor. Patients are given one day's supply of medicine and must return any unused drugs and a completed medicine accountability sheet. The Detox Team develops and implements a problem-oriented treatment plan and monitors patient's progress daily. If at any point in treatment the Detox Team believes the patient's medical or psychiatric condition warrants a transfer to in-patient status, such a transfer is immediately arranged and the above-stated in-patient protocol is followed.

At the conclusion of the alcohol detoxification period, as determined by clinical judgment aided by the AWS-SES, and Stinnett's treatment completion criteria,[14] the patient is discharged and medical follow-up, if necessary, is stressed in order to assure continuity of care.

Psychosocial Protocol of Ambulatory Detox Program

Staff serving on the treatment team as Nurse/Counselors are well aware that they have only the power which patients are willing to give them. Patients are assisted in problem-identification and aftercare planning. Our strongest confrontation is quiet and polite identification of discrepancies between the patient's stated goals, and ineffective behavior or inadequate plans to achieve these goals. The main focus at this stage of treatment, after medical symptoms are addressed, is acceptance of the illness of alcoholism by the patient. A willingness to participate in aftercare planning depends on the depth at which the patient accepts this single fact. Toward this end, we provide medical education, lectures, and exposure to a range of video presentations, exposure to the 'power of example' via A.A., and individual and group counseling with a reality-therapy orientation. Serious efforts are always made to intervene at the level of family systems and we encourage significant others' participation in concurrent treatment programs and/or Al-Anon and Adult Children of Alcoholics groups as well as Alateen or other appropriate referrals. Since some of our patients may show signs of emotional difficulties increasing as they withdraw from alcohol, or have a prior history of concurrent illnesses (both alcoholism and mental illness), we utilize the services of our psychiatric consultant to intervene appropriately with effective treatment for any psychopathology beyond the transitory symptoms normally associated with this stage of recovery from alcoholism. When psychopathology requires an in-patient admission to ensure adequate treatment or the safety of the patient or others, an appropriate transfer is obtained.

Data

Analysis of the initial ten month period between the opening of the Alcohol Ambulatory Detoxification Program on January 7, 1985 and the end of October, 1985 reveals a total patient enrollment of 267 patients of which 175 patients (66%) were out-patients and 92 patients (34%) were in-patients who received concurrent psychosocial treatment within our program.

The population that will be described from this point on are the 150 male and 25 female ambulatory detoxification patients. These patients ranged in age from 22 to 85 years old (average age 37.5 years). Nearly 43% of the patients were employed at the time they entered treatment.

The principle measure of therapeutic efficacy was the patient's clinical response as assessed by the AWS-SES, an index of severity for AWS. Application of this index allowed patients to be assigned a score based on their worst level of function during the previous 24 hours. A complete list of symptoms and explanation of the scoring system are given in Table 2. Table 3 gives the clinical features of alcoholic patients in the Ambulatory Alcohol Detoxification Unit at St. Mary's Hospital.

The average AWS – Symptom Evaluation Scores of the 175 ambulatory detox patients on Day 1 are found in Table 4.

Of the 175 patients admitted for ambulatory alcohol detoxification 5 or 2.9% had to be transferred to in-patient medical or psychiatric units – 2 patients had significant alcohol withdrawal, 1 patient had an UGI bleed, and 2 patients had acute psychiatric symptoms which had been masked by intoxication.

Table 2
CLINICAL FEATURES OF ALCOHOL WITHDRAWAL AND ASSOCIATED SCORING SYSTEM FOR ASSESSING THEIR SEVERITY*

Clinical Feature	*Scoring*
Seizure	0, none; 3, seizure within past 24 hours
Tremor	0, none; 1, tremor of hands and fingers with extension; 2, tremor of entire upper extremity with extension; 3, tremor without extension
Anxiety (fearfulness, apprehension, tenseness)	0, absent; 1, mild anxiety; 2, moderate anxiety; 3, acute panic state
Agitation	0, absent; 1, mild increase in motor activity; 2, fidgeting, restlessness, moderate increase; 3, inability to be still, pacing, thrashing, constant motor activity
Hallucinations (auditory or visual)	0, absent; 1, transient, patient knows that hallucinations are not real; 2, frequent or continuous, patient knows that hallucinations are not real; 3, transient and frequent or continuous, patient thinks hallucinations are real
Level of Consciousness	0, full alertness; 1, mild drowsiness, patient does not fall asleep; 2, marked drowsiness, patient intermittently falls asleep but awakens easily; 3, patient falls asleep, awakens with difficulty
Body Temperature (°F)	0, <98.6; 1, 98.7-99.5; 2, 99.6-100.6; 3, >100.6
Heart Rate (beats per minute)	0, 60-80; 1, 81-100; 2, 101-120; 3, >120
Diastolic Blood Pressure (mm Hg)	0, <90; 1, 91-99; 2, 100-109; 3, >110

*Adapted from Knott, et al.

The following criteria, as described by Stinnett, were used to determine treatment completion:

1.) The alcoholic should not consume alcohol during the treatment period.
2.) The severity of symptoms must show a progressive decrease over a reasonable length of time and reach a level that doesn't interfere with normal functioning.
3.) At the end of the withdrawal period, the patient should continue with some type of treatment for alcohol abuse.

One hundred and sixteen (66%) of the 175 patients who originally enrolled as out-patients met Stinnett's criteria for program completion. Their average length of stay was 8.73 days. Fifty-nine (34%) patients did not meet all of the criteria for program completion. Nevertheless, their average length of stay was 4.98 days.

Of the 116 patients who completed the program, we

Table 3
JOSEPH CENTER ATU: AMBULATORY PATIENTS

Moderate–Severe Clinical Features	*No. (%)*
Seizure	0 (0%)
Tremor	24 (13.7%)
Anxiety	70 (40.%)
Agitation	44 (25.1%)

Table 4
CLINICAL FEATURE AVERAGE SCORES, 175 AMBULATORY DETOX PATIENTS

Clinical Feature	*Scoring*
Seizure	0
Tremor	1.09
Anxiety	1.40
Agitation	1.00
Hallucination (auditory and/or visual)	0.07
Level of Consciousness	0.50

DAY 1 Vital signs were not scored as per Table 1, however, ranges and means were determined:

	Range	*Mean*
Body Temperature (°F)	96°-101°F	99°F
Heart Rate (Beats per Minute)	52-120 BPM	86 BPM
Blood Pressure: Systolic Range/ Diastolic	92-204/ 62-128	133/ 88

were able to verify attendance at a first aftercare counseling appointment within our clinic for 83 patients or 71% of program completers. An additional 23 patients (20%) accepted referral to outside treatment agencies, primarily for residential intensive treatment. Ten patients (9%) were referred to local A.A. groups without further professional treatment.

Of the 59 patients who did not meet all of the criteria for program completion, 49 patients, or 83% of non-completers, had either refused to develop aftercare plans or defected prior to attending a first scheduled aftercare appointment. Six patients (10%) were referred to outside agencies for aftercare despite failure to meet our program completion criteria fully.

Finally, 4 patients (7%) did return to attend a first scheduled aftercare appointment within our clinic despite failure to complete all program criteria. Non-Completers in the final two categories were often referred for failure to comply with program procedures despite the fact that they were clearing well medically.

Conclusion

This article has presented a description of a model for the ambulatory detoxification of alcoholic patients within a general community hospital setting. Analysis of data obtained from ten months of clinical experience demonstrates an overall average length of stay 7.47 days for 175 patients enrolled in the program. The program completion rate, using stringent criteria that required involvement in aftercare, was 66%. There were no incidents which compromised patient safety during this period.

Although our primary interest has been the development of an acute treatment option consistent with our philosophy of patient responsibility and family involvement, we are also aware of the importance of cost containment within the health care field.

This model represents, on average, a fifty percent reduction in cost for the detoxification process per day of treatment compared to in-patient hospitalization. Perhaps our experience will encourage others to replicate this cost-effective and clinically successful model within other communities.

ACKNOWLEDGEMENT: We are indebted to Drs. Robert Piscatelli, Paul Doolan, Louis Gottlieb, and Ralph Horwitz for their careful and thoughtful review of our manuscript and to Sister Margaret Rosita, Sister Marguerite Waite, Mr. William Appicelli, and Mr. Richard Benfer, without whose administrative support the Ambulatory Acute Treatment Unit of Joseph Center would not have been initiated.

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The Electrical Injury: Origins and Treatment Perspectives

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ABSTRACT– The high voltage electrical burn is a catastrophic event as well as a peculiar mode of injury. This report highlights the unique features of the electrical injury as well as presenting the origin of man's fascination with electricity both as a means of injury and of therapy.

Representative cases managed by the authors are illustrated to emphasize the differences between electrical and thermal injuries. An additional case is presented to stress the complexity of late reconstruction following severe electrical injury.

Introduction

The high voltage electrical burn is a catastrophic event as well as a peculiar mode of injury. This paper addresses the electrical injury first with regard to its origins and, then, the treatment of such burns, illustrating the difference between them and the more common thermal burns. Finally, clinical reports are presented to illustrate the points discussed.

Generally, electrical injuries can be divided into two categories:

1.) The household accident may kill by fibrillation, rarely requires the services of a plastic surgeon. The exception to this is, perhaps, the commissive burn in the child.
2.) The industrial accident, however, is not an insignificant problem. It carries with it a significant morbidity and mortality, as the statistics in Table 1 show.

Table I
ELECTRICAL INJURIES IN THE UNITED STATES
(1979)

- Exceed 3,000 per year
- 3 – 5% of Burn Center admissions
- Exceed 2,000 deaths per year
- Hospital mortality 36%

History

Man's fascination with electricity can be traced to ancient times. In fact, even earlier than 70 AD, the sacred books of the Hellenes tell the story of Salmoneus, King of Elias, who had the audacity to try to imitate lightning. This affront so outraged Zeus, that he destroyed Salmoneus with a salvo of thunderbolts, perhaps the first recorded case of death by electrocution.

Man's earliest confrontations with electrical phenomenon, other than lightning, are most likely related to the fossil resin called amber, a material which, when rubbed, will attract feathers, straw, and bits of paper. The Greeks referred to amber as "electron," because of its sunshine-like hues. In 1600, it was a physician named William Gilbert who first used the word electric to describe substances which behaved like amber.

From ancient times until the mid-eighteenth century, electricity remained a natural phenomenon, very much a mystery. The breakthrough was the development of the capacitor by Peter Von Musschenbroek in Leyden, 1846. The device, which came to be known as the Leyden jar, could create and store large quantities of electrical shock, an experience which he described in a letter to a friend as "like being rattled by a thunderbolt" and added that he would not take a second such shock for all the kingdom of France.

Electricity was soon seized upon by the medical profession for a variety of legitimate and not quite so legitimate purposes. Dr. James Graham, for instance, founded his "Temple of Health," dedicated to the eradication of impotence, or, as he termed it, "a relaxed indisposition of the parts." He claimed to achieve this goal through

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a variety of electrical and erotic practices, most of which centered around his medico-magnetico-musico-electrical bed or the Celestial Bed.

The harmful and even fatal effects of electricity were rapidly becoming known to practitioners of the time. Although reports of death by lightning date back to our old friend, Salmoneus, the first reported death by industrial electricity was that of a carpenter in Lyons, France in 1879. His autopsy listed cause of death as "a violent excitation of the vagus nerve."

Here in America, the first recorded death was that of Samuel W. Smith, in 1881, of Buffalo, New York. Mr. Smith apparently toured the city, finding the new generating plant while drunk, and passed out upon the generator and was electrocuted in front of many visiting dignitaries, including several New York State senators. The officials seemed most impressed by the fact that Mr. Smith died quickly and painlessly. It occurred to them that electricity could serve society in ways other than lighting the streets. As a result, in 1890, the State of New York tested a device which was to have a profound effect on one William Kemmeler and on the study into the nature of the electrical injury.

On August 6, 1890, Mr. Kemmeler, alias John Hart, became the first man to die in the State's new death chair, a device suggested as a means of capital punishment by those same local politicians from Buffalo, and constructed for the State by the Edison Laboratories.

The chair rapidly became a preferred method of execution and one enterprising man, Jimmy Thompson, developed a portable chair, which he transported on a truck from state to state, executing condemned men at various prisons and country fairs.

Although the chair seemed to work well, there was agreement as to the actual cause of death. Physicians flocked to executions and performed autopsies afterwards, seeking the exact nature of the electrical injury. In fact, until about 1920, just about all of our information concerning the pathologic effect of electricity came from the studies of such executions.

Discussion

Although electrical injuries are often compared to thermal burns, there are, in reality, several important differences as depicted in Table 2. The quantification of fluid needs cannot be based upon the percent of body area burned. Whereas the goal for urine output may be 50cc/hr with thermal burns, as much as 100cc/hr is required in electrical injuries because of the extent of myonecrosis with associated renal failure secondary to this muscle damage. Whereas in thermal burns, escharotomy may occasionally be required, the electrical injury, due to its deep nature, requires fasciotomy as the procedure of choice. And, while early excision and grafting is encouraged in thermal burns, the extent of the electrical injury is often unclear at first, and so early aggressive debridement is to be discouraged. Finally, because of the deep myonecrosis which often accompanies the high voltage injury, prophylaxis for *Clostridium* should be considered and mafenide acetate cream, by virtue of its deeper penetration through eschars, may be a more efficacious topical agent. These points are further illustrated in the following clinical examples.

Table 2
DIFFERENCES BETWEEN ELECTRICAL AND THERMAL INJURIES

- Quantification of fluid needs
- Fasciotomy versus escharotomy
- Hemoglobinurea - myoglobinurea
- Extent of debridement unclear
- Prophylaxis for Clostridia
- Mafenide acetate versus silver sulfadiazine

Case Report

Case 1: A 15-year-old boy grasped a high voltage power line with his left hand (Figure 1), suffering entrance wounds to the hand and exit wounds from the scapula and foot (Figures 2 and 3). Early fasciotomies of the forearm and hand were performed (Figures 4 and 5), but were unsuccessful in preventing myonecrosis. At 48 hours post injury, an initial limited debridement to apparently viable muscle was carried out (Figure 6). However, despite this, it soon became evident that the forearm was not salvageable, and a below elbow amputation was necessary in order to obtain a healed wound (Figure 7).

Case 2: A 22-year-old electrical lineman was stricken by a 7700 volt powerline across the left side of his head. The depth of the injury is revealed by the necrotic charred temporal bone (Figure 8). Exit wounds were out of both his feet. Debridement left the patient with bilateral guillotinic-type amputations (Figure 9), and a large area of exposed skull. The wounds were managed with a free omental flap to the scalp, covered by a split thickness skin graft (Figures 10–14) and split thickness skin grafts to both of his stumps.

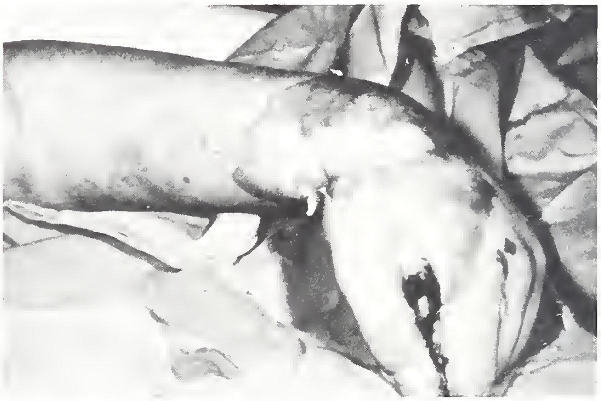
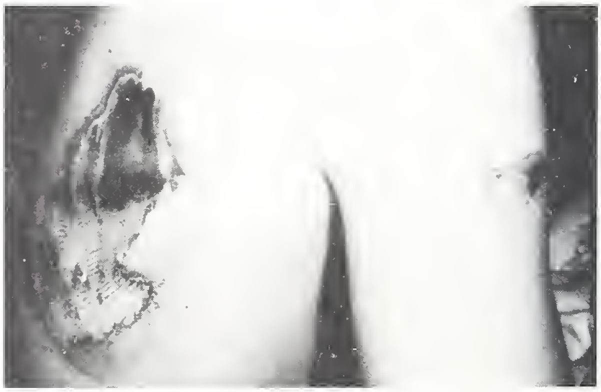


Figure 1



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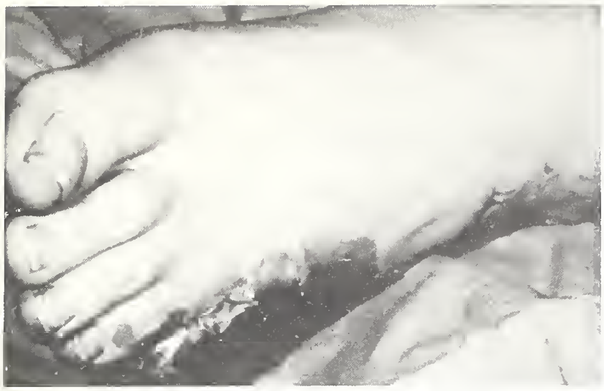

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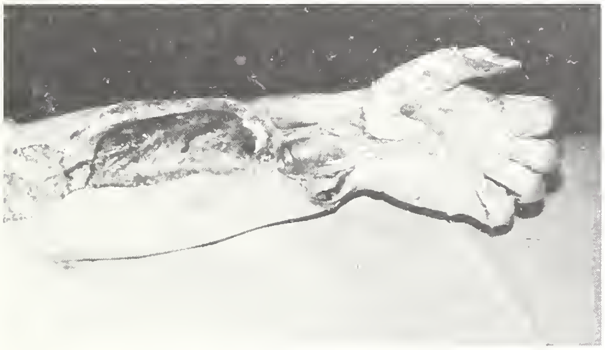

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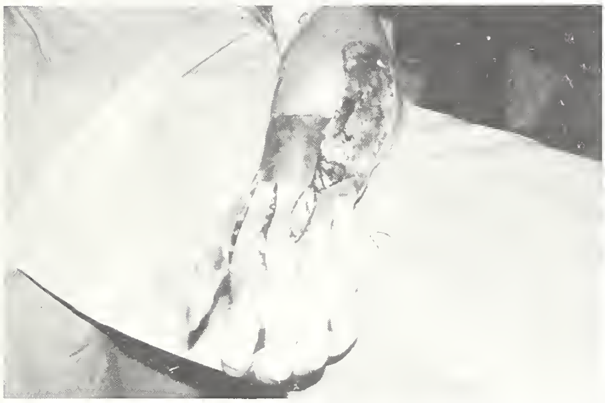

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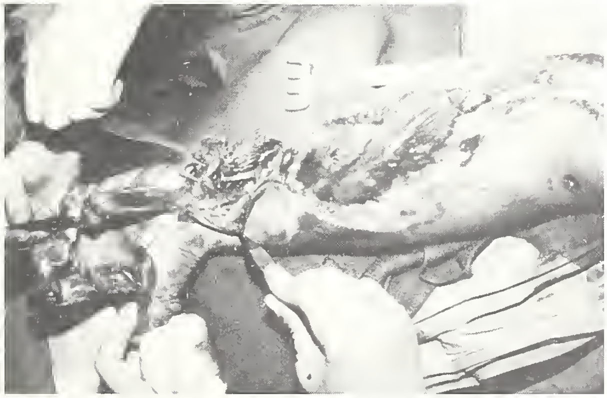

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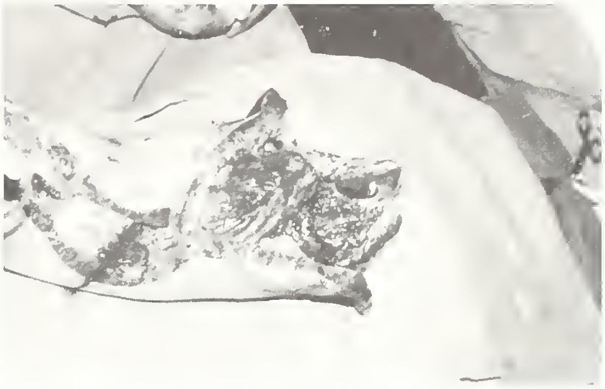

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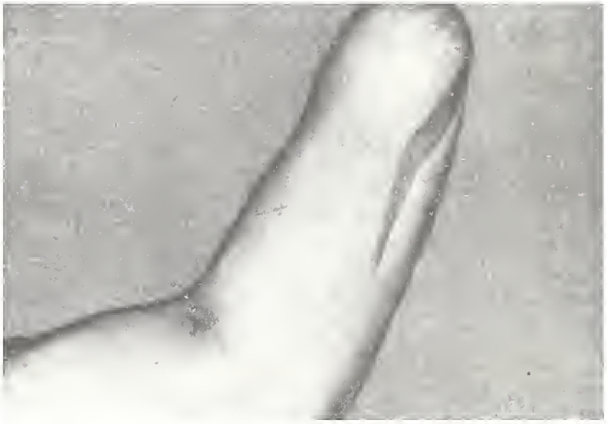

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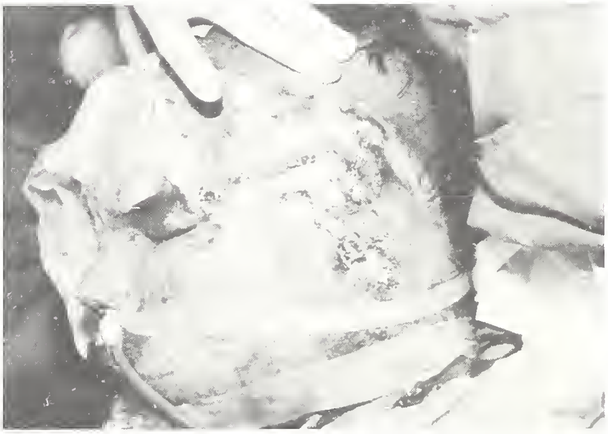
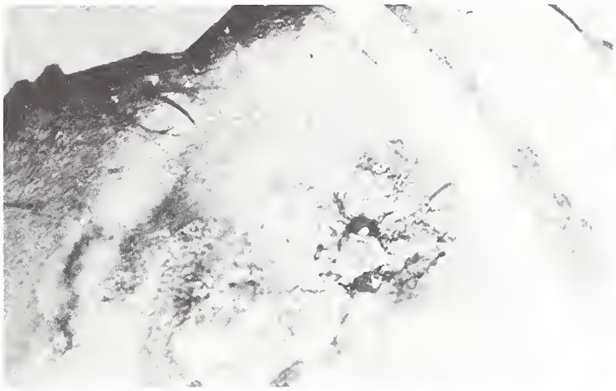


Figure 9

Summary

Man's fascination with electricity dates from time immortal. His actual understanding of it is rather recent, however. In between, especially as far as medical history is concerned, is an intriquing tale of misconception and misapplication.

It is a sad fact that, in any industrialized society, high voltage electrical accidents are inevitable. Successful resuscitation and treatment of such patients demands that



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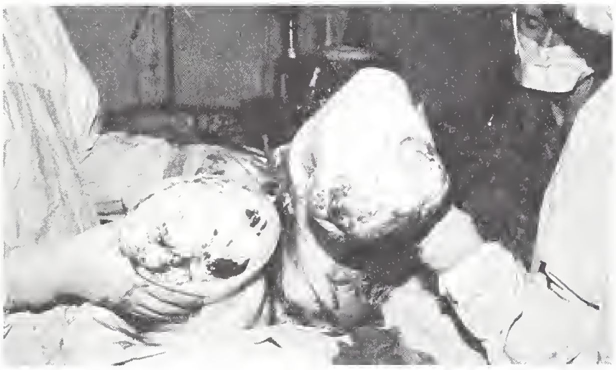

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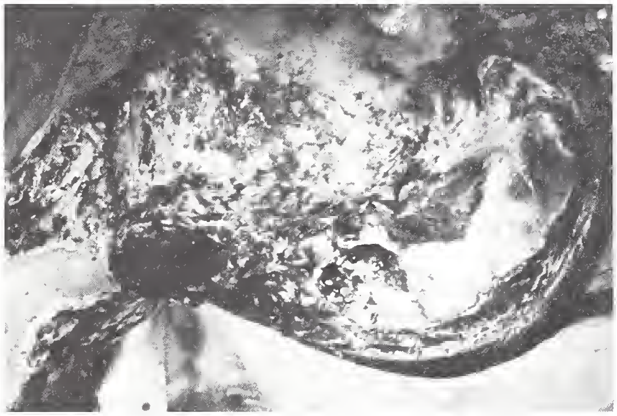

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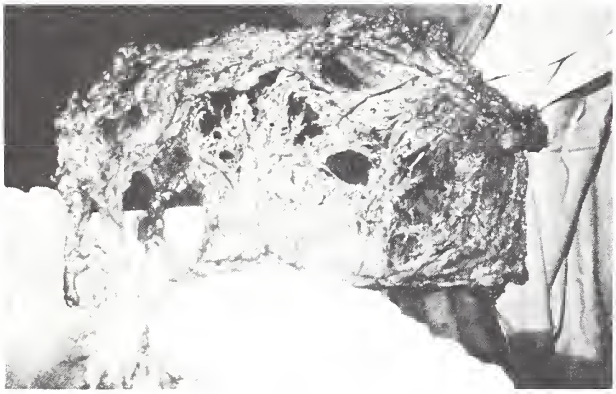

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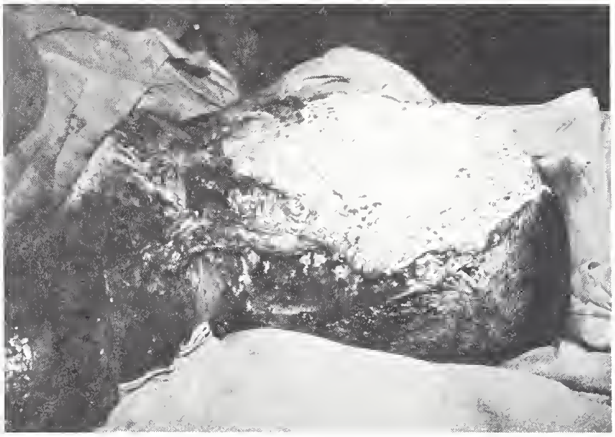

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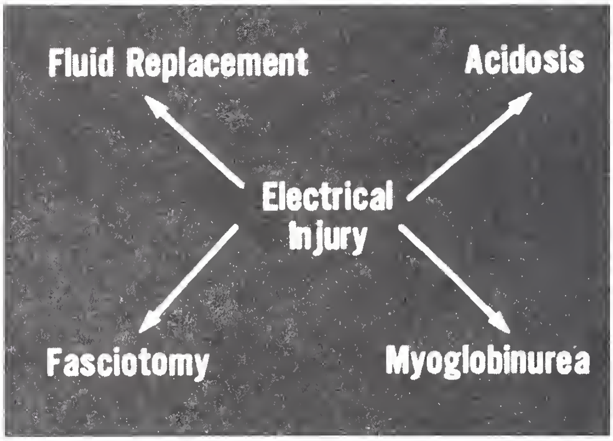

Fluid Replacement

Acidosis

Electrical Injury

Fasciotomy

Myoglobinurea

Figure 15

the physician understand the peculiarities of the electrical injury. These include, but are not limited to, problems with calculating fluid replacement, need for fasciotomy, the risks associated with muscle necroses, and the difficulty determining the extent of debridement required (Figure 15).

The role of the plastic surgeon in reconstructing such patients is increasingly more complicated and, in 1986, frequently demands the use of free tissue transfers and tissue expanders, in addition to the more traditional skin grafts and pedicle flaps.

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Experimental Segmental Pancreatic Allotransplantation: Efficacy of Aprotinin in Organ Preservation

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ABSTRACT— An experimental study of segmental porcine pancreatic allotransplantation was performed to assess allograft survival and function after 24 hours of cold storage with different preservation solutions. The possible benefit of donor pretreatment with aprotinin, a trypsin and kallikrein inhibitor, was also studied. Thirty transplants using six different preservation solutions were performed: Group I, a crystalloid solution (Euro-Collins); Group II, colloid (5% albumin in Euro-Collins); Group III, crystalloid (Euro-Collins) with donor pretreatment with intravenous aprotinin; Group IV, colloid (5% albumin in Euro-Collins) with aprotinin donor pretreatment (with or without aprotinin in the flush/storage solution); Group V, colloid (5% modified albumin); Group VI, colloid (5% modified albumin) with donor pretreatment with intravenous aprotinin (with or without aprotinin in the flush/storage solution). Only one of four allografts in the crystalloid-only group functioned, while 50 percent of all aprotinin-treated groups showed function. When all colloid groups were compared to the crystalloid-only groups, there was improvement in gland function. Both aprotinin and colloid improve allograft function in cold flush/stored pancreatic allografts.

Key Words: Pancreas preservation, aprotinin.

Introduction

Interest in transplantation of the pancreas has now spanned eight decades. The idea that pancreatic transplantation could be applied to the treatment of diabetes mellitus was described by Ssobolew in 1902,[1] almost 20 years before the discovery of insulin.

Gayet and Guillaumie[2] in 1927 proved that short-term endocrine function could be achieved in diabetic dogs using whole gland transplantation. Nearly forty years later, the first human whole gland pancreatic transplant was carried out by Kelly and Lillehei in 1966.[3]

Early attempts at segmental pancreatic allotransplantation were associated with frequent technical complications and high morbidity and mortality.[4] Newer techniques in handling the exocrine function of the pancreas and a reduction of vascular complications have generated renewed interest in segmental pancreatic allotransplantation. Reporting the results of 100 pancreas transplants performed at the University of Minnesota, Sutherland[5] concluded that enteric drainage of exocrine secretions gave better results than free ductal drainage or pancreatic duct obliteration.

Controversy still exists regarding the optimal technique for gland preservation. Cold storage and pulsatile machine perfusion techniques have been applied successfully to pancreas preservation, the former with somewhat better results.[6] Toledo-Pereyra has suggested that the ideal pancreatic preservation solution be hyperosmolar, hyperkalemic and hyperglycemic.[7] The work of Florack and

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co-workers suggests that colloid-containing solutions are superior to crystalloid solutions for hypothermic preservation of pancreatic tissue.[8] However, inadequate preservation, vascular thrombosis, and post-transplant pancreatitis continue to result in a significant incidence of early graft failure in clinical pancreatic allotransplantation.[5]

While the specific mechanisms responsible for inadequate organ preservation of the pancreas are incompletely understood, activation of pancreatic proenzymes within parenchymal tissue, resulting in pancreatitis, would seem one likely factor. Experimental work in animal models attests to the efficacy of aprotinin, a trypsin and kallikrein inhibitor, in preventing pancreatitis. In 1962, Hoferichter[9] found aprotinin effective in preventing acute necrotizing pancreatitis. Imrie and Mackenzie,[10] using a canine bile-induced pancreatitis model, have reported that a 100% mortality rate could be reduced to a 5% mortality rate with aprotinin treatment. Clinical trials have failed to confirm this efficiency, however. In 1968, Skinner[11] reported his findings on 99 patients at risk of developing postoperative pancreatitis. He concluded that aprotinin was of no benefit, with pancreatitis of a moderate to severe degree developing in 16 patients. Welbourn[12] found that aprotinin therapy had no effect on the death rate in a large multicenter trial.

It appears that aprotinin is effective in preventing pancreatitis, but only when it is present in pancreatic tissue at the time of (or shortly after) the insult which would otherwise initiate pancreatitis. We thus postulated that donor pretreatment with intravenous aprotinin prior to operative manipulation and harvest of the pancreas would improve subsequent hypothermic graft preservation. In the experiments reported below, three basic preservation solutions were tested with and without donor pretreatment with aprotinin: a standard intracellular electrolyte solution (Euro-Collins), Euro-Collins solution plus albumin, and an extracellular electrolyte solution (modified normal saline solution) plus albumin.

Materials and Methods

Thirty pigs with an average weight of 17 kg received segmental pancreas allografts from random porcine donors. Operations were performed under light halothane anesthesia and succinylcholine (1-2 mg/kg) for muscle relaxation. Arterial blood pressure was continuously monitored via a left carotid arterial cannula. Intravenous access and central monitoring were achieved via a left external jugular catheter; this line was maintained postoperatively for vascular access. Controlled ventilation was provided by endotracheal intubation.

The body and tail of the pancreas were obtained from random donor pigs for segmental allotransplantation. The pancreatic allografts had an arterial inflow system comprised of the celiac, splenic, and hepatic arteries, and venous outflow via the splenic vein. Immediately after harvesting, the allografts were flushed with ice-cold solution at a hydrostatic pressure of 30-40 cm H_2O until cleared of blood (250 ml of solution over 3-5 min) and then stored in that same solution at 4°C until allotransplantation 18-24 hours later. Transplants were placed in the right lower quadrant of the recipient's abdomen. Previous work in this laboratory has shown that an arterial conduit consisting of donor celiac and hepatic artery interposed in the recipient external iliac artery provides better long-term patency in porcine pancreatic allografts than an end-to-side anastomosis of donor splenic artery to recipient external iliac artery.[13] The donor splenic vein was anastomosed in an end-to-side fashion to the recipient external iliac vein. A total pancreatectomy of the recipient's native pancreas was performed. Finally, in allografts appearing viable following completion of the vascular anastomoses and the native total pancreatectomy, a distal jejunal Roux-en-Y pancreaticojejunostomy was performed to provide drainage of pancreatic exocrine secretions. In glands of questionable viability by gross appearance, the duct of the donor pancreas was allowed to drain freely into the recipient's peritoneal cavity.

The immunosuppressive regimen consisted of intravenous azathioprine (100 mg) and intravenous methylprednisolone (125 mg) on the operative day. Oral immunosuppression was started on the second postoperative day and consisted of azathioprine (50 mg) and prednisolone (10 mg). Ranitidine (75 mg) twice a day was given with meals to lessen gastric ulcer formation. Graft function was assessed by periodic postoperative fasting blood glucose determinations as well as intravenous glucose tolerance tests[14] and In^{III} platelet scans.[15]

The 30 animals were divided into six groups. In Group I, pigs received pancreas allografts flushed with Euro-Collins solution and stored in the same solution. Group II grafts were flushed/stored with 5% albumin in Euro-Collins. Group III donors were pretreated with intravenous aprotinin (5,000 kallikrein inhibitor units [KIU]/kg) one hour prior to pancreatectomy; grafts were then flushed/stored with Euro-Collins solution. In Group IV, donors were pretreated with intravenous aprotinin and grafts were flushed/stored with 5% albumin in Euro-Collins solution. Group V grafts were flushed/stored with 5% albumin in modified normal saline solution (normal saline with glucose and hydrocortisone added). Finally, Group VI donors were pretreated with intravenous aprotinin, and the grafts were flushed/stored in 5% albumin in modified saline solution. In several Group IV and Group VI animals, aprotinin was also added to the flush/storage solution (100 KIU/ml).

Successful gland preservation (function) was defined by at least one normal fasting blood glucose level ($\leq$ 150 mg/dl) during the postoperative period. The experiment was terminated when the pig died, or when persistently elevated blood sugars ($>$ 150 mg/dl) prevailed and the animal was terminated. A post mortem was performed on all animals. The allografts were studied grossly and microscopically for evidence of vascular complications, pancreatitis, and rejection. Statistical calculations were performed using Chi-square analysis. Euro-Collins solution (an intracellular electrolyte composition) was prepared by adding 70 ml of 50% dextrose to 1 liter of Travenol Renal Electrolytes.[16] A 5% albumin solution in Euro-Collins was prepared by adding 50 ml of 25% human serum albumin (Cutter) to 200 ml of Euro-Collins solution. Sixty-two mg of hydrocortisone was also added. An extracellular electrolyte preservation solution with 5% albumin was prepared by adding 1 ml of 50% dextrose and 62.5 mg of hydorcortisone to 250 ml 5% human serum albumin solution. The composition of these different solutions is listed in Table 1.

These experiments were performed under the Animal Care Guidelines of the United States Department of Agriculture and the Hartford Hospital.

Table 1

COMPONENTS OF FLUSH/STORAGE HYPOTHERMIC PRESERVATION SOLUTIONS

	Euro-Collins	*Euro-Collins + 5% Albumin*	*Modified Albumin*
Albumin (gm percent)	0	5.4	5.08/dl
Osmolarity (mOsm/l)	375	334	265
Sodium (meq/l)	10	43	138
Potassium (meq/l)	115	79	1.0
Chloride (meq/l)	15	13	106
HCO_3 (meq/l)	10	–	–
Dextrose (g/l)	35	–	2
Phosphate (meq/l)	100	–	–
Hydrocortisone (mg/l)	–	–	233.6

Results

The experimental results are summarized in Table 2. Only one out of four glands in Group I showed even transient function postoperatively. These glands typically appeared soft prior to revascularization. Upon revascularization, little or no bleeding was encountered when intraoperative biopsies were taken, and no gland edema was noted prior to wound closure. Group III glands (crystalloid flush and storage with donor pretreatment with aprotinin) showed a modest improvement in function. Four out of six glands functioned, but this difference was not significant ($p > 0.05$).

Table 2

GRAFT FUNCTION FOLLOWING HYPOTHERMIC PRESERVATION WITH DIFFERENT FLUSH/STORAGE SOLUTIONS

	Function	*Nonfunction*
I. Euro-Collins	1	3
II. Colloid/Euro-Collins	0	2
III. Euro-Collins/Aprotinin	4	2
IV. Colloid/Euro-Collins/Aprotonin	4	1
V. Colloid/5% Modified Albumin	4	2
VI. Colloid/5% Modified Albumin/ Aprotonin	6	1

Because of the small number of animals in each group, no statistically significant intergroup difference can be found among Groups I through VI. However, interesting trends are noted when groups are combined for analysis, as seen in Table 3. The results suggest improved function when colloid and/or aprotinin are components of the flush/storage solutions, regardless of the electrolyte composition of these solutions.

Table 3

GROUPED COMPARISON OF FLUSH/STORAGE HYPOTHERMIC PRESERVATION SOLUTIONS

Solution	*Function*	*No Function*	
Intracellular Electrolytes	9	8	} $p > 0.05$
Extracellular Electrolytes	10	3	
Albumin	14	4	} $p < 0.05$
No Albumin	5	7	
Aprotinin	14	4	} $p < 0.05$
No Aprotinin	5	7	

Discussion

The development of methods for preservation of pancreatic tissue has relied heavily on work done on kidney preservation. Yet, optimal methods for kidney preservation may not be efficacious for pancreas preservation. For example, in kidney preservation machine perfusion and cold flush/storge methods are equivalent if donor warm ischemia time is not prolonged.[17,18] However, Florack[6] has found that cold flush/storage of the pancreas provides better pancreas preservation than pulsatile perfusion. In similar fashion, it is possible that optimal electrolyte composition and osmotic and oncotic pressure properties of organ preservative solutions may be different for each organ system, for cold flush/storage versus hypothermic pulsatile perfusion, and perhaps for different animal models. Continued organ-specific research to determine optimal long-term hypothermic preservation solutions would seem warranted at this time.

Using a cold flush/storage preservation method of 24-hour segmental pancreas preservation, we found that intravenous administration of aprotinin to the donor one hour prior to pancreatectomy appeared to improve subsequent organ preservation. In addition, colloid-containing preservation solutions appear superior to crystalloid solutions, regardless of the presence or absence of aprotinin.

We propose that trypsin, released by acinar tissue, initiates a cycle of microvascular thrombosis, tissue ischemia, acinar necrosis, and the further release of trypsin and other activated proteolytic enzymes. Upon revascularization, Group I pancreases (intracellular crystalloid only) had a pale, non edematous appearance with minimal parenchymal blood flow, consistent with vascular plugging and parenchymal necrosis. Aprotinin, a trypsin inhibitor, has been found to improve renal blood flow in a canine pancreatitis model by preventing microvascular thrombosis.[19] Thus, aprotinin may be beneficial in hypothermic pancreatic preservation both by a direct effect (preventing proteolytic destruction of the gland) and by an indirect effect (preventing microvascular thrombosis).

No significant difference could be demonstrated in pancreatic preservation solutions with "extracellular" electrolyte composition compared to "intracellular" electrolyte composition. This is consistent with the work of Hoffmann and associates in a canine model for hypothermic pulsatile perfusion of kidney transplants.[20] The relative amounts of sodium or potassium did not make any difference in allograft preservation and subsequent function after transplantation. Of interest, this is also the first report of successful organ preservation using a preservation solution based on a synthetic colloid (low molecular weight hetastarch). Excellent preservation for up to 70 hours was observed.

In summary, an experimental study of segmental porcine pancreatic allotransplantation was performed to assess allograft survival and function. Aprotinin treatment of the pancreas donor prior to organ harvest appears to be beneficial in improving postoperative gland function. Preservation solutions containing colloid were superior to crystalloid solutions. The electrolyte composition (intracellular versus extracellular) of the flush/storage solutions did not appear to be an important factor. Possible mechanisms for the protective effect of aprotinin are the inhibition of autolysis due to enzymes activated either during or upon revascularization at the time of transplant and the prevention of microvascular thrombosis.

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The Benefits and Risks of Intraabdominal Drainage

RANDALL K. JONES, M.D. AND ISIDORE COHN, JR., M.D.

Drainage of the abdomen is a useful procedure employed both prophylactically and therapeutically. It is important for surgeons to understand the purpose of drainage, the types of drains available, the risks of drainage, and the proper management of intraabdominal drains. Appropriate use of drains for specific indications is an integral part of patient care.

Intraabdominal drains have been used for centuries for a variety of reasons, with varying degrees of success. Since the Roman nobleman Aurelius Celsus first placed brass tubes through the abdominal wall to drain ascites,[1] indications for drainage have multiplied. By 1887 Robert Lawson Tait could proclaim, "When in doubt, drain."[2] Current therapy dictates more specific and limited use of intraabdominal drains. Risks and benefits of intraabdominal drainage are understood better now, and new techniques and drains have been devised. The questions of when and how to drain now require a more critical evaluation with assessment of all available options.

Purpose of Drainage

Before an intraabdominal drain is placed, the purpose it will serve should be clear. Therapeutic drainage is used for collections of pus and/or extravasations of body fluids. The drain provides a means for evacuation and collapse of a potential space, reducing further complications of undrained pus or a fluid collection. An extension of therapeutic drainage is the concept of prophylactic drainage, in which drainage of a space is established to prevent possible fluid collection or abscess formation in situations where a physiologic fluid (blood, bile, urine) may collect or when an anastomosis or closure of an organ may leak.

Some goals of drainage are inappropriate and are mentioned now only to be condemned. Use of a single drain for drainage of the peritoneal cavity in diffuse peritonitis is futile. As early as 1905, Yates[1] demonstrated that peritoneal drains would be sealed off within approximately 6 hours. Later, Agrama and colleagues[3] demonstrated how various types of drains are walled off from the peritoneal cavity shortly after placement.

Drainage is not a substitute for good surgical technique or hemostasis. Classical indications specify drainage for diffuse capillary ooze that has failed to respond to hemostatic agents, but Lazarus and colleagues,[4] reporting a poll of surgeons, found uncontrollable intraperitoneal oozing a rare problem.

Types of Drains

The ideal drain eliminates dead space, continuously removes fluid, and has a low risk of associated complications.[5] This requires the drain to exhibit certain physical properties. It should be soft and pliable to prevent erosion into adjacent organs. It should be smooth and produce little, if any, tissue reaction to prevent its attachment and allow easy removal. The drain should be constructed from a material that will not decompose or change character after prolonged exposure to body fluids and tissue.[6]

Drains are classified according to their mechanism of action. Outflow drains allow passive escape of fluids by providing a site of egress. Examples include the simple tube drain, the corrugated rubber drain, and the Penrose drain. They are usually placed dependently to allow gravity to work in concert with pressures within the abdominal cavity. In addition, the Penrose drain uses the capillary action in its lumen to effect drainage.[7]

Closed-suction drains actively remove fluid by exerting a negative pressure at the site to be drained. The Jackson-Pratt and Hemovac drains are examples of this type. Depending on the suction apparatus used, between 20 and 80mmHg negative pressure can be generated at the end of the drain.[8] Because these drains do not require dependent positioning to be effective, they are particularly useful in the pelvis.[9]

Closed-suction drains often become occluded with tissue sucked into the orifices, which has led to the development of the open-suction or sump drain. A second, smaller tube was incorporated into the drain to act as a vent, so the drain could not suck tissue into its hole but would still remove fluid.[10-12] There are many variations of this type of drain, with such modifications as a bacterial filter over

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an inlet or a 3rd lumen to infuse an irrigant. Examples include the Saratoga, Axiom, Davol, and Shirley sump tubes. Regardless of the modification of the sump drains, low levels of suction pressure are preferred. Baker and associates[13] showed that the contamination of *in vitro* wound models was a direct result of high-volume suction (Figure 1).

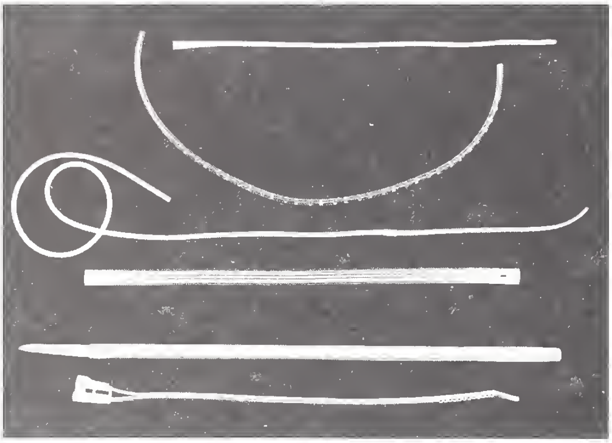

Figure 1

Most drains are placed in the operating room, but an increasing number are being placed in the radiology suite. The ability to guide needles under fluoroscopy, CT, or ultrasonography into collections inside the abdominal cavity offers a viable alternative to laparotomy under certain conditions. Most drains placed in this fashion are simple, modified (corkscrew, pigtail, etc.) tube drains, usually no greater in diameter than 14 F.[14]

Complications of Drains

Drains are not innocuous, and many complications have been reported related to their use. Drains are foreign bodies and as such provoke a reactive exudate as well as the development of granulation tissue around the drain tract. This tissue reaction usually prevents entry of organisms from the skin into the peritoneal cavity. Fibrous adhesions resulting from this inflammation can lead to bowel obstruction.[15]

If tissue reaction does not take place, a secondary drain tract infection and/or abscess can occur. Nora and coworkers[16] reported that approximately 20% of cultures taken from drains placed in the abdominal cavity grow organisms from the interior end of the drain.

Drain fever, as described by Myers,[17] is a complication produced by manipulation of drains in place longer than 72 hours. Drains of less pliable material, often sump drains, have a tendency to erode into adjacent vessels or organs, leading to hemorrhage and fistula.[6]

In a 5-year prospective study, Cruse and Foord[18] reported infection rates as follows: clean undrained wounds 1.53%, closed wounds with suction drains 1.8%, and Penrose drains through an adjacent stab wound 2.4%. However, if the Penrose drain was brought through the wound itself, the infection rate rose to 4%.

Drains brought through the incision increase the probability of incisional hernia.[7] Abdominal wall hernia also can occur at the stab wound site made for drain placement. One of the more distressing complications of drainage is a retained drain—one that breaks off below the skin level during extraction or that migrates into the abdomen. This can be prevented by securing the drain to the skin with a stitch (Figure 2), and by making sure that the stab wound is of adequate size to allow the drain to be removed without undue tension. Other drain-related complications include superficial drain site infections[16] and persistent pneumoperitoneum.[19]

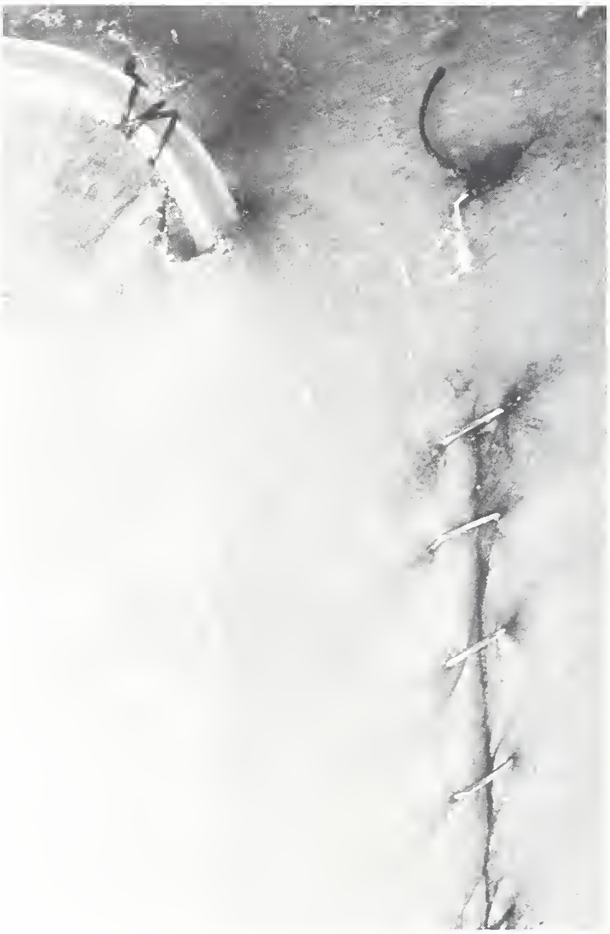

Figure 2

Management of Drains

Management of intraabdominal drains follows several general principles.[20]

- Drains should be positioned where fluid is expected to collect, but not in contact with suture lines.
- The route of the drain should be as direct and short as possible.
- When the goal of drainage has been accomplished, the drain should be removed. There is a direct correlation be-

tween drain-related complications and the length of time the drain is in place.

- Drainage through operative incisions should be avoided.
- At the time of removal, a drain placed for infection or abscess should be advanced intermittently over a period of days. Drains placed for other reasons can usually be removed completely at one time without adverse sequelae. Drains placed prophylactically should be removed as soon as the risk of the complication they were placed to prevent has passed.

Specific Indications

Biliary surgery. Several studies have shown that drainage after cholecystectomy is not always necessary. Indications for drainage include acute cholecystitis, common bile duct exploration, other concomitant major procedures, and incomplete hemostasis in the gallbladder bed. In the absence of these indications Gordon and others[21] demonstrated that there were neither advantages nor disadvantages to draining the gallbladder bed after cholecystectomy. Maull and colleagues[22] demonstrated an actual increase in the rate of complications in patients who were drained. Williams and associates[23] noted that it is safe to omit the drain if there is no blood or bile oozing from the gallbladder bed and if the cystic duct and artery are absolutely identified and doubly ligated under direct vision (Figure 3). Most surgeons agree that any major liver resection should be accompanied by some form of drainage, because of the certainty of bile ooze.

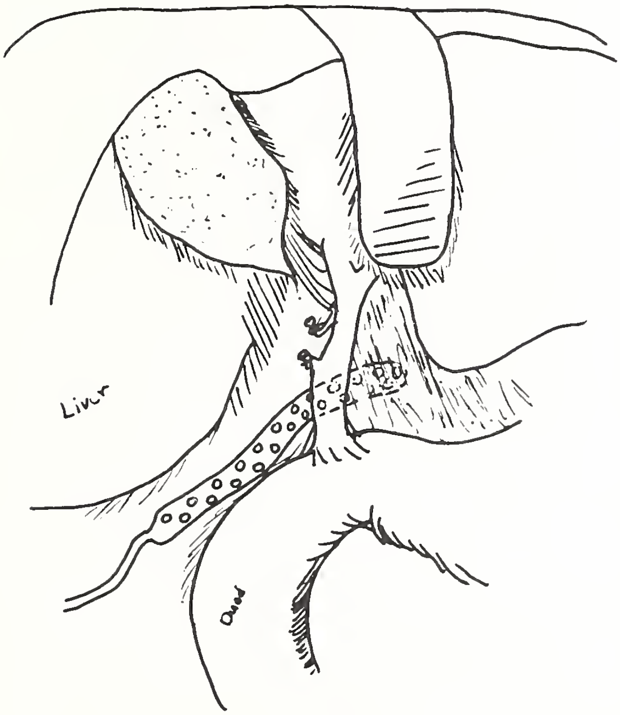

Figure 3

Pancreatic surgery. Surgeons demonstrate their respect for pancreatic fluid by placing drains any time the pancreatic capsule has been invaded. This includes biopsy as well as trauma, which does not disrupt the capsule but results in a subcapsular hematoma. The consequences of undrained pancreatic enzymes (pseudocyst, pancreatic ascites) are of sufficient seriousness to render drainage a minimal risk by comparison. While drainage can result in a pancreatic fistula, this is a much simpler problem to manage.[15]

Splenectomy. Several studies from the 1960s demonstrated as much as a 5-fold increase in incidence of subphrenic abscess following routine drainage after splenectomy.[24-27] Currently, if the wound is dry drains are not employed, unless it is thought that there has been a concomitant injury to the pancreas. Closed-suction drains are usually recommended to overcome the negative intraabdominal pressure in the subphrenic area.[9]

Intestinal anastomoses. Bowel suture lines do not need routine drainage, therapeutic or prophylactic. Indeed, Berliner and co-workers[2] showed that drains can be a cause of an anastomotic leak. Occasionally, drainage in the region of raw, weeping surfaces may be necessary to prevent perianastomotic fluid collections.

Gastric surgery. Gastric suture lines do not require drainage. If the duodenal stump is scarred or inflamed, however, the duodenal stump closure may be tenuous. A closed-suction drain can be placed close to but not touching the bowel or suture line. This prophylactic drain should be left in place for at least 8 to 10 days, after which a duodenal stump leak is unlikely.[7]

Appendectomy. There is no good evidence that drainage is of benefit for the nonperforated acute appendix or the perforated appendix with diffuse peritonitis.[28,29] However, drainage of the localized abscess, secondary to a perforated and walled-off appendix, is mandatory, particularly in the critically ill patient. If good drainage can be established, appendectomy need not be done, and the patient's condition can be stabilized. Later, an elective interval appendectomy can be done.[15]

Gynecologic surgery. Drainage is limited to 2 specific occasions in gynecologic surgery: when a patient has a perforated tuboovarian abscess, and when, in the presence of severe pelvic infections, a drain is placed into the space of Douglas to prevent fluid accumulation and subsequent abscess.[11]

Percutaneous drainage techniques are inappropriate when fungal infections are suspected, as they will not drain well.

Trauma surgery. Even after adequate surgical debridement, traumatized tissue may still contain devitalized areas predisposed to infection and/or rupture. Suction drains placed prophylactically often become therapeutic by draining blood, bile, pus, pancreatic fluid, urine, or bowel contents. If no drainage occurs, the drain should be removed after 48 to 72 hours.[11]

Renal surgery. If there is a suspected ooze of blood or urine, suction drainage is indicated.

Abdominal abscess. In abdominal abscess, available management options include exploratory laparotomy, local surgical exploration and drainage, and percutaneous catheter drainage. The latter technique combined with radiographic guidance has been demonstrated to be effective in certain settings.

Attempts at using radiographic guided placement of drains is reported to be between 47% and 85% successful in various series. [14,30,31] This alternative to surgical drainage should be considered when the patient faces high operative risk or when the patient's abdomen would be difficult to explore because of previous surgery.

Indications for percutaneous drainage of an intraabdominal abscess require that the drain must not traverse bowel, uncontaminated organs, or the uncontaminated peritoneal or pleural spaces. The abscess should not communicate with the gastrointestinal tract or lie deep in the pelvis. Percutaneous techniques are inappropriate when fungal infections are suspected, as they will not drain well.

Most authors recommend that the abscess be single and nonloculated. [14] If these criteria are not met, it is best to proceed directly to surgical drainage. If surgery is performed, care should be taken to ensure adequate drainage is obtained at the time of operation in order to preclude further development of undrained infection from the abscess.

Summary

Several questions need to be answered when abdominal drainage is being contemplated.

- What is the goal to be accomplished by drainage?
- Do the benefits of drainage outweigh the risks of nondrainage or drain-related complications?
- What type of drain will best accomplish drainage?
- What technique should be used to place the drain?
- By what method should the drain be managed?

A clear understanding of these considerations is the basis of good clinical judgment and will decrease the risk and optimize the benefit of intraabdominal drainage.

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Important Advances in Clinical Medicine

Epitomes of Progress—Pathology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in pathology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in pathology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Pathology of the California Medical Association and the summaries were prepared under its direction.

Immunohistochemistry and the Diagnosis of Spindle Cell Neoplasms

The histologic diagnosis of poorly differentiated or unusual neoplasms by traditional methods may be difficult, relying on routine paraffin-embedded, hematoxylin-eosin-stained tissue sections augmented by special stains or ultrastructural examination or both. Recent advances in immunohistochemistry have added another dimension to tumor evaluation, giving immunologic clues to the diagnosis and decreasing the volume of cases previously examined by electron microscopy.

The antibodies generally used in immunohistochemistry are myriad, directed against structural "intermediate filaments" (keratin, vimentin, desmin, neurofilaments and glial fibrillary acidic protein), enzymes (such as neuron-specific enolase), other proteins (such as factor VIII, S-100) and other material. The literature, replete with immunologic characterization of various tumors, shows that few, if any, antibodies that have been developed are actually "specific" to a particular tumor. Despite this, immunohistochemistry is a powerful tool, especially when used to answer specific questions or to narrow a differential diagnosis formulated by review of more traditionally prepared material.

For example, the differential diagnosis of a spindle cell neoplasm arising in deep soft tissues and growing in long, sweeping fascicles includes fibrosarcoma, synovial sarcoma, leiomyosarcoma and malignant schwannoma. A battery of immunoperoxidase stains would show vimentin positivity in each because all are felt to be mesenchymal origin. Of the four, only synovial sarcoma expresses cytokeratins—a finding similar to only three other mesenchymal tumors: mesothelioma, epithelioid sarcoma and adenomatoid tumor. The smooth muscle-derived leiomyosarcoma generally expresses desmin, whereas malignant schwannoma, being of neural crest derivation, reacts for S-100 protein. If all of the stains were negative (except for vimentin) then fibrosarcoma would be seriously considered.

The differential diagnosis of spindle cell tumors that occur more superficially in the subcutis or cutis includes melanoma, squamous carcinoma and several mesenchymally derived neoplasms including dermatofibroma, dermatofibrosarcoma protuberans, leiomyoma and leiomyosarcoma. Melanoma may be distinguished by its expression of S-100 protein and vimentin, while epithelial-derived squamous carcinoma produces only cytokeratin. The smooth muscle tumors show desmin and vimentin positivity whereas histiocytic markers such as α_1-antitrypsin, lysozyme and α_1-antichymotrypsin are generally found in dermatofibroma and dermatofibrosarcoma protuberans.

As techniques improve and antibodies are developed that are more tumor-specific, immunohistochemistry will become an even more powerful tool, improving the reproducibility of diagnosis in these and other difficult tumors.

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Weiss SW, Langloss JM, Enzinger FM: Value of S-100 protein in the diagnosis of soft tissue tumors with a particular reference to benign and malignant Schwann cell tumors. Lab Invest Sep 1983, 49:299-308.

Barrett's Esophagus

Barrett's esophagus is the eponym for replacement of the squamous epithelium of the distal esophagus by columnar epithelium. This replacement is now considered to be an acquired metaplasia that follows the epithelial injury caused by chronic gastroesophageal reflux and can therefore often be associated with strictures or peptic ulceration of the esophagus. The exact prevalence is not known, but Barrett's esophagus is found in about 10% of patients undergoing esophagoscopy for symptoms of reflux.

On histologic examination, Barrett's esophagus has a heterogeneous appearance and comprises a variety of cell types similar to gastric and intestinal epithelial cells. A distinctive histologic pattern of goblet cells interspersed among columnar mucous cells is common and virtually diagnostic of Barrett's esophagus. Other patterns resemble gastric fundic or cardiac mucosa and can thus be interpreted as Barrett's esophagus only when the site of biopsy is definitely the esophagus and not a hiatus hernia.

This condition is clinically important because of its association with esophageal adenocarcinoma. In recent studies, a 30 to 40 times increased risk was estimated when Barrett's esophagus is present. Because these figures are based on a relatively short follow-up period, the actual risk may be even higher. Such considerations have led to the suggestion that biopsies be done regularly on patients with Barrett's esophagus to look for epithelial dysplasia, which, as a putative precursor of adenocarcinoma, would serve to identify those patients at highest risk for malignancy. Problems with this suggestion include the lack of well-defined histologic criteria for recognizing dysplasia and distinguishing it from reactive or regenerative changes. Nevertheless, high-grade dysplasia has recently been shown to represent a morphologic marker of risk for esophageal adenocarcinoma.

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The Carcinoma-Carcinoid Spectrum

In the past decade we physicians have become aware that carcinoid tumors show a much wider clinicopathologic spectrum than previously thought. This has given rise to a plethora of new terms, some of which, such as apudoma, neurochristoma and neuroendocrinoma, are based on their postulated neuroectodermal derivation; others, such as neuroendocrine carcinoma, on their clinical behavior, and a group, such as gastrinoma, on their secretion products. Because these tumors are morphologically distinctive, I see no point in changing Obendorfer's original terminology, and thus I designate these lesions as carcinoids and specify their differentiation and secretion products (Table 1).

Table 1
NOMENCLATURE AND CLASSIFICATION OF PURE AND MIXED ENDOCRINE CELL TUMORS

- Carcinoid tumors
  - Well differentiated
  - Moderately differentiated
  - Poorly differentiated
    - Small cell (oat cell)
    - Large cell
- Mixed (composite) glandular-endocrine cell carcinoma
  - Microglandular-goblet cell carcinoma
  - Scirrhous-argyrophil cell carcinoma
  - Adenoendocrine cell carcinoma
- Amphicrine cell carcinoma

On histologic examination, some tumors may show atypical features such as glandular profiles, a spindle cell pattern, squamous or osteoid metaplasia or pleomorphism with frequent mitoses and necrosis. In rare cases they may be poorly differentiated and resemble undifferentiated large-cell or small-cell carcinoma (oat cell carcinoma) and lymphoma. As is well known, some carcinoids are associated with well-defined syndromes, such as the carcinoid or the Zollinger-Ellison syndromes, due to the secretion of amines or peptides. Immunohistochemical analysis of these tumors has shown that, whereas one amine or peptide may predominate, such as serotonin or gastrin, most are multihormonal. These findings are also seen with the clinically silent carcinoids such as the foregut and hindgut tumors. Furthermore, the immunohistochemically shown amines and peptides in the primary tumor do not necessarily correspond to those found in the overlying endocrine cells or in metastatic lesions.

Although the presence of scattered endocrine cells within adenomas and carcinomas of the gastrointestinal tract has been known for some time (in as many as 20% of all colonic carcinomas), there are a number of tumors in which there is a large admixture of endocrine and epithelial cells. Thus, the strict separation of gut mucosal tumors into carcinoma and endocrine tumors has had to be modified to include those tumors with admixtures of varying proportions of endocrine and epithelial cells. These tumors have been designated as mixed or composite tumors and have been further subdivided into several distinctive histologic types (see Table 1). Some of these tumors, such as the microglandular-goblet cell carcinoma, have a distinctive clinical behavior, whereas others, such as the scirrhous-argyrophil and adenoendocrine cell carcinoma, appear to behave in a manner similar to the corresponding carcinoma. Finally, there is a further distinctive tumor type, namely the amphicrine tumors. These differ from the mixed tumors in that endocrine and epithelial cell constituents are present within the same cell. These findings support the hypothesis that epithelial and endocrine cells of the gut share a common cell of origin.

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Lymphocyte Gene Rearrangements—A New Technique in the Diagnosis of Lymphoma

The histopathologic diagnosis of lymphoma can be difficult, particularly when the disease presents at extranodal sites. Conventional microscopic or immunohistochemical studies often prove inadequate for the evaluation of T-cell infiltrates, of neoplasms lacking appreciable atypia or where a superimposed inflammatory process obscures the underlying malignant process.

Recent insights into the molecular biology of lymphocytes have led to the development of a technique that provides an objective estimate of the clonal composition of lymphoid infiltrates. Almost all lymphomas are monoclonal populations, the progeny of a single transformed progenitor cell. Reactive infiltrates, in contrast, are polyclonal. The clonality of a lymphoid cell population can be determined by analyzing the structure of genes that code for immunoglobulins in B cells or for the antigen receptor molecules of T cells. These genes undergo precise rearrangements during lymphocyte development, assuming a different structure in each clone of lymphoid cells. By evaluating the type and number of such rearrangements in DNA extracted from a clinical biopsy specimen, the presence of any predominant B- or T-lymphocyte clone can be readily detected. When present, such clonal proliferation implies malignancy. Clonal populations constituting as few as 5% of the infiltrating cells can be shown by this method. Several researchers have shown that the pattern of gene rearrangements present in a lymphocyte population also gives evidence of its lineage (T versus B cell) and degree of differentiation.

Because cutaneous lymphoid infiltrates represent a notoriously difficult diagnostic problem, we applied this technique to a broad spectrum of such lesions. Skin biopsy specimens of mycosis fungoides, a cutaneous T-cell lymphoma, were found to contain a monoclonal T-cell infiltrate, as did the peripheral blood of patients with Sézary's syndrome, a form of chronic T-cell leukemia. Clonal T-cell proliferation has also been identified in several rare conditions whose relationship to T-cell lymphoma is controversial, such as lymphomatoid papulosis and granulomatous slack skin. This technique also permitted reliable distinction between the polyclonal lesions of cutaneous pseudolymphoma and the monoclonal infiltrates of cutaneous B-cell lymphoma. The analysis of gene rearrangements can therefore provide both scientific insights and an objective diagnostic aid in the evaulation of lymphoid cell infiltrates of the skin.

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Hodgkin's Disease—Controversies 1986

The cell of origin in Hodgkin's disease remains a mystery, but recent data from a number of laboratories shed additional light on the subject. The issue is of more than academic interest because it also involves the question of the role of markers in the diagnosis of Hodgkin's disease. The morphologic diagnosis of Hodgkin's disease is relatively noncontroversial, but there is a surprising error rate in diagnosing Hodgkin's disease. A recent study found an error rate of 13%. This figure would appear to be unacceptable given the current level of therapeutic success with this disease.

The antibody Leu M1, originally defined as a myelomonocytic marker, has been increasingly utilized as a marker of Hodgkin's disease following a number of recent reports of its presence in Reed-Sternberg cells and their variants. Two major questions have arisen over these data. Weak or absent staining in cases of lymphocyte-predominant Hodgkin's disease has led some authors to conclude that this disorder is unrelated to the other forms of Hodgkin's disease. But recently Hsu and co-workers have suggested that the cells are simply more mature and as a consequence have sialylated the antigen. Using neuraminidase treatment, they removed the terminal sialic acid residues and found the antibody Leu M1 was present in most cases of lymphocyte-predominant Hodgkin's disease. The second major question concerns the specificity of the reaction. The original reports found little evidence of staining for the antibody in non-Hodgkin's lymphomas, but a recent study shows that many of the peripheral T-cell lymphomas most likely to be confused with Hodgkin's disease did stain for it.

The second question above is of practical significance. Grouping the results from all of the articles in question suggests that at least a portion of peripheral T-cell lesions contain the antibody. For those with access to frozen section or plastic section immunophenotyping, the application of standard B & T reagents can generally resolve the differential. With only paraffin blocks available, there are still some markers that will help resolve the question of peripheral T-cell lymphoma versus Hodgkin's disease. These include a number of markers commonly seen in Hodgkin's disease, but seen infrequently in T-cell lymphomas, such as HLA-DR/Ia, cathepson B, lysozyme, α_1-antitrypsin, peanut agglutinin and concanavalin A.

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Monitoring Cervical Carcinoma With Fine-Needle Aspiration Biopsy

Despite major advances in diagnosis and treatment, cervical carcinoma continues to be a disease of major epidemiologic importance, with an estimated 16,000 new cases each year and an annual mortality of 7,000. Rational surgical or radiotherapeutic treatment of invasive cervical carcinoma depends on accurate initial staging and subsequent surveillance for occult persistent and recurrent disease. Most recurrences occur early and in areas palpable by pelvic examination. If disease has not spread beyond the central pelvis, pelvic exenteration can offer long-term survival, even in women with recurrent cervical carcinoma. Follow-up of patients with cervical cancer traditionally has been by physical examination, exfoliative cytology and radiologic examinations. Recently some have advocated adding fine-needle aspiration biopsy (FNAP) to the list of procedures that may be effective in detecting persistent or recurrent disease in patients with cervical cancer.

The principal advantages of FNAB over open surgical biopsy for following patients with cervical cancer are rapid reporting of results, minimal morbidity and complications and good patient tolerance. In women with cervical carcinoma, FNAB may be particularly useful in distinguishing between radiation fibrosis and tumor.

In our experience at San Francisco General Hospital Medical Center and the University of California, San Francisco, in utilizing FNAB to monitor patients for persistent or recurrent disease, FNAB led to definite changes in patient management for half of those whose biopsy results were abnormal. Abnormal results on FNAB can be useful in making decisions regarding chemotherapy and radiotherapy. Perhaps the most important use of the procedure is to select suitable patients for pelvic exenteration. In several of our patients considered to be candidates for exenteration, malignancy on FNAB of a lymph node outside the true pelvis led to cancellation of the procedure.

Patients with cervical cancer who have suspicious or benign findings on an FNAB specimen may require further workup. In cases wherein the initial FNAB specimen shows insufficient tissue or suspicious but not diagnostic changes, a repeat FNAB or open surgical biopsy should be done. It is also worth remembering that normal findings on a smear on FNAB does not entirely rule out the possibility of recurrent tumor; if the clinical presentation is suggestive, repeat FNABs or surgical biopsies may be appropriate for follow-up.

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Plasma Cholesterol Levels Determined by Lipoprotein Interactions With Cell Surface Receptors

Plasma cholesterol levels are regulated primarily by the activity of specific lipoprotein receptors on various cells throughout the body, but especially within hepatocytes. Lipoprotein receptors mediate the uptake and degradation of the various plasma lipoproteins. There are at least two distinct hepatic lipoprotein receptors: the apolipoprotein (apo)-B,E(LDL [low-density-lipoprotein]) receptor and the apo-E receptor, which is postulated to be the chylomicron remnant receptor. They are independently regulated and display unique ligand specificity. In addition, the apo-B,E(LDL) and the apo-E receptors differ in apparent molecular weight (130,000 and 56,000, respectively). Both receptors, however, possess a region within their amino acid sequence that is enriched in acidic amino acids (glutamate and aspartate) and that is postulated to be the ligand binding domain. The tentative identification of acidic amino acids within the receptors as being essential in mediating ligand interactions is based primarily on data showing that basic amino acids (lysine and arginine) of the ligands (apo-E and apo-B) mediate receptor binding.

The receptor binding domain of apo-E has been localized to basic amino acids in the vicinity of residues 140 to 160. Naturally occurring variants of apo-E with single amino acid substitutions in this region of the molecule are defective in their abilities to bind to the lipoprotein receptors and predispose affected persons to type III hyperlipoproteinemia. Recently it has been possible to more clearly define essential residues within this region of the apo-E molecule by using site-specific mutagenesis. A natural extension of the studies defining the receptor binding domain of apo-E has been the identification of two basic regions of apo-B that appear to mediate the interaction of this apolipoprotein with lipoprotein receptors.

Eventually it will be possible to develop a model describing ligand-receptor interactions; presumably these occur through the interaction of key acidic amino acids of the receptors with the key basic amino acids of apo-B and apo-E.

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Small-Cell Carcinoma of the Ovary With Hypercalcemia

Small-cell carcinoma of the ovary is an unusual ovarian tumor that was once thought to be extremely rare but is now being recognized with increasing frequency. It occurs in young women, average age in the early 20s, with a range of 12 to 39 years. Approximately 50% of the cases have been associated with hypercalcemia, which is usually asymptomatic. The patients when further evaluated do not have hyperparathyroidism. The lesions grossly are gray-white, solid, with focal areas of hemorrhage and necrosis. On microscopic examination, the tumor consists of sheets of neoplastic cells with scant intervening connective tissue and scattered cystic spaces of varying sizes filled with pale eosinophilic material and lined by the tumor cells; these somewhat resemble graafian follicles. On ultrastructural examination, the cells frequently have numerous junctions and only rare microvilli on the free surfaces.

Scully originally coined the term "small cell" to distinguish this lesion from the more common poorly differentiated ovarian adenocarcinoma with which it can be confused histologically. The latter, however, occurs in an older patient population, is not usually associated with hypercalcemia and does not have such a uniformly poor prognosis. In addition, the cells in a poorly differentiated ovarian adenocarcinoma are about twice the size of the cells in a small-cell tumor. The cellular origin of this lesion is still undetermined, various experts favoring an epithelial, gonadal stromal or germ cell origin. To date, no dense core secretory granules have been reported in this lesion.

Various therapeutic modalities, including surgery, chemotherapy and radiation therapy, in different combinations have been used in these patients to no avail. Most cases have been clinically stage I-A at the time of diagnosis and, in spite of this, the prognosis is dismal, with death usually occurring within months. This tumor needs to be recognized and separated from the more common poorly differentiated ovarian adenocarcinoma because of its poor prognosis, association with hypercalcemia, occurrence in young women and resistance to all current modes of therapy.

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Immunohistology for the Rapid Diagnosis of Viral Infections

The development of increasingly aggressive and successful cancer therapy, the proliferation of organ transplant programs and the appearance of the acquired immunodeficiency syndrome have combined to place large numbers of immunocompromised patients at risk for potentially lethal viral infections. Fortunately, effective antiviral agents are becoming available. Their successful use, however, requires rapid and specific diagnosis.

Seroconversion is slow, intrinsically undependable in these patients and possibly irrelevant to the immediate clinical problem. Routine cultures are also slow and may merely reflect viral shedding rather than significant tissue involvement.

Pathologists' approach to the diagnosis of viral infection has traditionally been to identify characteristic cellular cytopathic effects, predominantly viral inclusions and associated alterations such as cellular enlargement, multinucleation and chromatin margination. This approach is valuable but does have disadvantages. False-negative results reversed by subsequent culture isolation may be distressingly frequent, especially with cytomegalovirus (CMV). Diagnostic cellular changes are probably absent in early infections in which the institution of therapy may be most beneficial. It is clear that viral nucleic acid and antigens are present in many cells that lack inclusions. In contrast, reactive alterations such as cellular enlargement and prominent nucleoli may produce false-positive results. Even when present, viral features may be recognizable without allowing specific virus identification, an increasingly important problem as effective antiviral agents with a narrow spectrum of activity are developed. For instance, acyclovir is eight to ten times less effective against varicella zoster virus (VZV) than against herpes simplex virus (HSV). Unfortunately, these two viruses cannot be distinguished on the basis of a Tzanck preparation or routine histologic or electron-microscopic examination.

Rapid direct identification of specific viruses through immunologic staining of tissue sections and smears has been hampered by limited antibody availability, though it has been feasible for many years. Monoclonal antibodies, some commercially available, are now making direct viral diagnosis practical. For example, we have found that the sensitivity of antibody C5 (Genetic Systems, Inc, Seattle/Syva Company, Palo Alto, California) in detecting CMV in frozen sections from open-lung biopsy specimens is essentially equal to that of culture or in situ nucleic acid hybridization. Other antibodies from these companies have been extremely valuable in the direct rapid diagnosis of VZV and HSV infections because they recognize glycoprotein antigens that withstand formalin fixation and paraffin embedding. A monoclonal antibody to the adenovirus hexon protein (C. Cepko and P. Sharp, Massachusetts Institute of Technology, Cambridge) and a polyclonal antibody to respiratory syncytial virus (Burroughs Wellcome Company, Research Triangle Park, NC) have also performed well. So many laboraties are now developing antibodies that soon all major viral pathogens will probably be directly detectable in tissue, even following routine fixation and processing.

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Chlamydia trachomatis—Diagnostic Techniques

Chlamydia trachomatis is a fastidious obligate intracellular parasite. The organism has been implicated as the causative agent in a variety of genital infections—including cervicitis, salpingitis, prostatitis and epididymitis—in upper respiratory tract infections and in conjunctivitis in infants. Chlamydia is effectively treated with antibiotics, but clinical manifestations may be nonspecific and subtle, and the organism has been difficult to detect.

Culture yields the highest detection rate with about 80% sensitivity, but culture is tedious and delays initiation of therapy. Special techniques are needed, making culture costly and not readily available in most laboratories.

Cytologic examination of secretions has proved to be an insensitive procedure for detecting *Chlamydia*. Cellular changes are generally nonspecific, leading to both false-positive and false-negative results. Adding iodine staining does not appreciably improve detection rates. Immunoperoxidase staining has recently been coupled with cytology, and results with this technique have varied. Technical difficulties with sample size, cell loss and nonspecific staining have precluded its widespread use.

Microimmunofluorescence for detecting antibody is both sensitive and specific for the organism. Special techniques, however, are required for its performance, and, like culture, microimmunofluorescence has not been available in most laboratories.

Direct fluorescent antibody staining for *Chlamydia* using fluorescein-conjugated monoclonal antibody to detect extracellular elementary bodies is probably the most promising procedure to date. The procedure can be used directly on smeared secretions or to enhance detection of the organism in culture and is both sensitive and specific for the organism. While not yet universally available, the procedure does not require sophisticated technical expertise and is inexpensive to do, making it more attractive to most laboratories.

Chlamydia trachomatis is difficult to detect. Direct fluorescent antibody staining appears to be the most promising, rapid and cost-effective technique at present, but, for any procedure to be effective, a heightened clinical awareness of the organism in high-risk populations is needed.

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Lymphoma—Correlating Morphology and Clinical Course of Disease

Major conceptual advances have recently been made regarding non-Hodgkin's lymphomas. These advances relate to a greater understanding of the immune system and the normal mechanisms of lymphocyte function. With this newly acquired knowledge, alternative classification systems for the malignant lymphomas have been proposed, based on modern immunologic concepts. New diseases have been described, and new approaches to the management of patients with lymphoma have been suggested. About 70% to 75% of lymphomas are of B-lymphoid origin, most arising from the cells that normally compose the follicular or germinal center of the node.

About 20% to 30% of lymphomas are of T-lymphoid origin. In an attempt to correlate these concepts with clinical behavior, a translational tool was recently proposed, termed the "Working Formulation for Clinical Usage." In this system, lymphomas are divided into low-, intermediate- or high-grade tumors.

The low-grade lymphomas consist primarily of the follicular small-cleaved tumor (also known in the Rappaport system as nodular, poorly differentiated lymphocytic) and the lymphomas of small lymphocytes (also known as chronic lymphocytic leukemia, or well-differentiated lymphocytic lymphoma). These tumors are clinically indolent in behavior, with prolonged patient survival in spite of widely disseminated disease. Using multiagent chemotherapy, the group from Stanford has found that patients with low-grade lymphomas are not curable in the traditional sense, although they may be expected to live for five to ten years or more in the presence of active underlying lymphomatous disease. While in unusual cases a patient with localized (pathologic stage I) disease may be curable with radiation therapy, chemotherapy, consisting of single-agent alkylators or the cyclophosphamide-vincristine-prednisone regimen, is reserved for patients whose disease has become symptomatic or anatomically precarious.

The concept of prolonged survival in the presence of active disease is not valid in the lymphomas of intermediate- or high-grade type. These tumors, by natural history, are more aggressive and require intensive therapy at the time of diagnosis. Without the benefit of therapy, such patients would be expected to live less than a year. Newer regimens of multiagent chemotherapy have recently been described, however, that may result in long-term disease-free survival and possibly cure. These regiments, including the M-BACOD (methotrexate alternating with a combination of bleomycin, doxorubicin [Adriamycin], cyclophosphamide, vincristine [Oncovin] and dexamethasone) or similar therapies, have resulted in complete remission in about 60% to 70% of patients, with long-term, disease-free survival in about 50% of all treated patients. The specific details regarding optimal therapy in these patients depend on the specific subtype of disease, extent of disease and presence or absence of various prognostic indicators.

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Rectal Suction Biopsy in the Diagnosis of Congenital Megacolon

When we think of procedures used for either ruling in or ruling out the diagnosis of congenital megacolon (Hirschsprung's disease), biopsy of the muscularis propria of the rectum comes to mind as the procedure of choice. While muscularis biopsy is undoubtedly highly accurate, there are several drawbacks. It requires admission to hospital and general anesthesia. The operation may result in inflammation and scarring that make subsequent pullthrough operations difficult. The frozen tissue section, on which a pathologist is asked to make a pronouncement as to the presence or absence of ganglion cells, is generally of a poorer technical quality than well-fixed paraffin-embedded permanent sections. As a result, immature ganglion cells may not be recognized.

An alternative to muscularis biopsy is mucosal suction biopsy. The procedure avoids the disadvantages of muscularis biopsy in that anesthesia is unnecessary and the rectal wall is not incised. Only small fragments of mucosa and submucosa are obtained, which are fixed, embedded and stained in the routine manner.

The rationale behind this procedure is based on the fact that the submucosal (Meissner's) plexus bears a constant relationship to the myenteric (Auerbach's) plexus. During fetal development the submucosal plexus is populated by primitive neural elements that migrate from the underlying myenteric plexus. Therefore, the presence of ganglion cells in the submucosal layer assures their presence in the myenteric plexus. Their (ganglion cells) presence, no matter how immature, rules out Hirschsprung's disease.

The diagnostic accuracy of this procedure depends on the recognition of the characteristic morphology of the neural units composing the submucosal plexus and the appearance of ganglion cells in all their stages of maturity. Accuracy also depends on the adequacy of the sample obtained. There are some drawbacks to the method relating mostly to the size of the sample obtained and the failure to recognize immature ganglion cells. In my experience, however (more than 60 rectal biopsies), and that of others, the procedure has been highly accurate in determining the presence, or absence, of rectal ganglion cells. The technique may be further enhanced by the recent successful application of the peroxidase-antiperoxidase technique for the demonstration of neuron-specific enolase in immature ganglion cells and nerve trunks in rectal suction biopsies.

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Immunohistology and In Situ Hybridization in the Diagnosis of Hepatitis B

Immunohistology and in situ hybridization have increased our understanding of the pathogenesis of hepatitis B. Histologic examination, unlike serologic studies, reveals the cellular and subcellular distributions of viral antigens within the liver and the relationship of virally infected cells to inflammatory cells. Serologic markers of viral infection, however, are generally clinically sufficient for diagnostic purposes as well as being more readily available or economical. Immunohistologic study is done by incubating tissue sections of liver biopsies with antiserum against viral antigens such as hepatitis B surface antigen (HBsAg), hepatitis B core antigen (HBcAg) and the more recently discovered α-antigen. The binding of the specific antiserum to virally infected cells is visualized by immunohistochemical procedures such as the immunoperoxidase technique or by immunofluorescence. HBsAg is present in the cytoplasm of infected liver cells, whereas HBcAg is predominantly, but not exclusively, located in the nuclei of hepatocytes. The α-antigen is also primarily present in the nuclei of hepatocytes. HBsAg and HBcAG are present in proportions inverse to the amount of inflammation in infected livers. Thus, the panlobularly inflamed livers of patients with acute hepatitis B often lack immunohistologic evidence of HBsAg or HBcAg, whereas increasing amounts of these antigens are found as the inflammation decreases through the spectrum of chronic active hepatitis to chronic persistent hepatitis. In liver biopsy specimens of patients with chronic active hepatitis, HBcAg is generally present in a much larger percentage of hepatocytes than is HBsAg, although the converse may occasionally be the case. A search for both HBsAg and HBcAg will reveal one or the other antigen in at least 90% of percutaneous liver biopsy specimens from patients with serologic evidence of hepatitis B-related chronic active hepatitis, α-Agent infection, always present in conjunction with hepatitis B, has been reported to be very common in fulminant cases of hepatitis occurring in homosexual persons and intravenous drug abusers, and immunohistology is helpful for the study of autopsy tissues when serum may no longer be available.

In situ hybridation for the detection of the hepatitis B genome may offer further insights into the pathogenesis of hepatitis B-related diseases. In situ hybridization can be done on routinely fixed and processed paraffin-embedded tissue. Labeled DNA strands that are complementary to the DNA of the hepatitis B virus are used as probes for detecting viral DNA within infected hepatocytes. Future study will elucidate the histologic relationship of the hepatitis B virus genome to actively expressed hepatitis B viral proteins and aid in the search for latent hepatitis B infection in patients with idiopathic chronic hepatitis.

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In Situ Hybridization in Diagnostic Pathology

When a lesion cannot be diagnosed by routine light microscopy of hematoxylin-eosin-stained sections, a surgical pathologist turns to such ancillary techniques as special histologic stains, immunohistochemistry and electron microscopy, which often prove helpful in identifying cellular proteins, secretory products and ultrastructural features specific for the tissue type or lesion in question. The extraordinary advances in the field of molecular biology have recently rendered another cellular constituent accessible to a pathologist's scrutiny – namely, nucleic acids, the genetic material itself. Recombinant DNA technology has made available a wide variety of DNA probes that can be used to detect target genes by specifically annealing to complementary sequences of DNA or RNA. However, the standard research technique of hybridization to purified DNA on filters ("Southern blots"), using radioactive probes, presents serious time, expense and safety disadvantages for routine clinical use.

Two recent discoveries have now brought this technology into the realm of diagnostic surgical pathology: the nonradioactive labeling of DNA probes with biotinylated nucleotides and the finding that cellular DNA and RNA in tissue sections and cytologic smears remain accessible as targets for probe hybridization, even after formalin fixation and paraffin embedding. Thus, essentially all routinely processed pathologic specimens can be examined for the presence of specific nucleic acid sequences by in situ hybridization directly on a microscope slide.

Diagnostic applications thus far have focused mainly on the infectious diseases, proving most useful in cases not expressing the usual markers of infection. For example, the technique has identified hepatitis B virus DNA in cases serologically negative for surface antigen, herpesvirus DNA in ganglia during the "latent" viral state and cytomegalovirus (CMV) DNA in cells showing no CMV inclusions on routine histologic examination. Other studies have detected CMV DNA in Kaposi's sarcoma lesions, human papillomavirus DNA in cervical condylomas and dysplasias and JC virus DNA in progressive multifocal leukoencephalopathy.

In situ hybridization can also be used to quantitate changes in intracellular levels of specific messenger RNAs characteristic of certain neoplasias. For example, differential hybridization of a DNA probe complementary to thyroglobulin messenger RNA has been used to distinguish benign and malignant thyroid lesions. Also, the transcription of specific oncogenes is known to be increased in some cancers, and the recent availibility of biotinylated oncogene probes suggests exciting new applictions of the technique. In this way, in situ hybridization should prove to be not only a useful diagnostic adjunct, but also a powerful tool for gaining insight into the molecular pathogenesis of many important lesions.

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Stereotactic Brain Biopsy

Recent advances in imaging techniques (computed tomography [CT] and magnetic resonance imaging [MRI]) in localizing brain lesions have been accompanied by an increasing use of stereotactic brain biopsy as a means of diagnosis. This has great appeal. Stereotactic brain biopsy permits a tissue diagnosis on a specimen obtained without craniotomy, under local anesthesia and with very little risk. In our first 500 stereotactic biopsies, there has been one death (0.2% mortality).

Stereotactic biopsy presents a pathologist with a new kind of specimen. The typical specimen consists of two or three 1-mm^3 fragments. While the small size of the specimen is intimidating to a pathologist when first faced with it, it is usually adequate for diagnosis. The great advantage of the stereotactic biopsy specimen is that it is obtained from a predetermined CT-MRI target point within the lesion and therefore provides optimal material. This greatly differs from an open biopsy where a neurosurgeon takes tissue from the periphery of a lesion that may be difficult to localize at craniotomy.

Interpreting stereotactic biopsy requires a pathologist experienced in the technique, the neurosurgeon who did the biopsy and the CT-MRI scan. Interpretation is always done with complete knowledge of clinical and radiologic findings. A smear made from a part of the specimen is almost always the first step. The remainder of the specimen is processed depending on what the smear shows. There is usually adequate material for electron microscopy, cultures and permanent sections.

Stereotactic biopsy has proved to be extremely accurate in our hands for the diagnosis of brain neoplasms. While sampling presents an obvious problem, the diagnosis in most cases is more than adequate for decisions regarding treatment. We have had good success in differentiating between toxoplasmosis and malignant lymphoma in patients with acquired immunodeficiency syndrome who present with mass lesions. Stereotactic biopsy has been less accurate in the diagnosis of inflammatory lesions of the brain.

One of the major problems with stereotactic brain biopsy is that it is likely to be a rare procedure in all but the largest hospitals. This restricts the ability of a neurosurgeon and a pathologist to develop and maintain competence in the technique. We process two to three cases per week, which is close to the minimum number necessary to maintain expertise.

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Dysplastic Nevi

The incidence of malignant melanoma has been increasing steadily in recent years. Much effort has been expended in improving the early diagnosis of malignant melanoma. This has become especially important in view of the nearly 100% survival in patients with thin (less than 0.76 mm) malignant melanoma lesions when compared with the 40% to 50% survival of patients with very thick (greater than 3.5 mm) lesions. On histopathologic examination, benign nevi have often been associated with and presumably are the precursors of malignant melanoma. In addition, a clinically increased number of benign nevi has been implicated as a strong risk factor for the development of malignant melanoma.

A distinctive nevus, the dysplastic nevus, has been associated with familial malignant melanoma, with a dominant mode of inheritance being postulated. In this setting, nevi tend to be numerous, numbering 25 to 75 per patient. Dysplastic nevi are often larger than other nevi, commonly measuring greater than 0.5 cm with irregular borders. The color of dysplastic nevi is variegated tan to dark brown to pink. Dysplastic nevi are most common on the trunk, but occur not uncommonly on the scalp, buttocks and breast. Although the likelihood that any individual dysplastic nevus may undergo malignant transformation is very low, patients with familial melanoma with the dysplastic nevus syndrome have a lifetime incidence of melanoma approaching 100%.

In diagnosing dysplastic nevi, the histologic criteria include nested junctional melanocytes present in an irregular pattern with horizontal bridging from one rete ridge to the next, random cytologic atypia of the melanocytes, dermal fibroplasia and dermal lymphocytic host response.

Because patients with familial melanoma and dysplastic nevi have been identified as having a high risk for malignant melanoma developing, careful follow-up of all clinically atypical pigmented lesions is undertaken. Photographic follow-up of these lesions aids in identifying lesions that have changed recently; these are then excised.

More controversial is the subject of sporadic dysplastic nevi. Epidemiologic studies are in progress to determine the risk of malignant melanoma developing in patients with one to many dysplastic nevi in a nonfamilial setting.

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A Marker for Monoclonality of T-Cell Malignancy

Pathologists have frequently been confronted with the difficulty of establishing a definitive diagnosis of malignancy in patients with possible lymphoproliferative disorders. The presence of monoclonal surface membrane immunoglobulin and clonal rearrangements of immunoglobulin genes, even in the absence of functional gene expression, has greatly aided in the diagnosis of B-cell malignant tumors. In contrast, the lack of a clonal marker for T-cell malignancy has impaired our ability to make a definitive diagnosis in many cases and has limited our understanding of the biology and natural history of T-cell diseases.

An important development within the past two years is the discovery of a marker for monoclonality of T-cell neoplasms. T cells have been shown to have a receptor that is expressed during development. Analysis of the DNA coding for the β-chain of this receptor has shown that rearrangements of the gene occur early in T-cell development. The T-cell receptor gene is rearranged and transcribed only in T cells, including helper, suppressor and killer T cells, and is analogous to the immunoglobulin gene rearrangement occurring during B-cell differentiation. If a large enough clone of T cells is present (1% to 5%), the uniform DNA configuration of their T-cell receptor genes allows identification of the clone. Patterns of gene rearrangement, identified by Southern blot hybridization with gene probes, are used as markers to determine monoclonality or polyclonality of given T-cell proliferations.

Clonal rearrangements have been detected in diffuse aggressive peripheral T-cell lymphomas and in T-cell acute lymphoblastic leukemias and lymphoblastic lymphomas. Mycosis fungoides is a disorder in which the histologic diagnosis is often difficult. Clonal rearrangements have been reported in histologically confirmed biopsies and also in biopsy specimens of enlarged lymph nodes that were not clearly histologically involved, suggesting that clonal populations that cannot be recognized by routine histologic and immunologic methods may be detected by gene rearrangement studies. Most T-cell chronic lymphocytic leukemias also have clonal rearrangements, confirming the neoplastic nature of this disease. A nonrearranged or germ-line configuration of the T-cell receptor gene has been found in B-cell lymphomas, nonlymphoid malignant lesions and normal cells from patients with T-cell neoplasms. The existence of a clonal marker T cells obviously has important implications for diagnosis and potentially for the prognosis of and therapy for T-cell malignant disorders.

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Human Papillomavirus Infection and Cervical Neoplasia

In recent years the genital human papillomaviruses (HPV) have been recognized as sexually transmitted pathogens of major epidemiologic importance and as oncogenic viruses playing a pivotal role in the pathogenesis of cervical neoplasia.

The incidence of genital HPV infection has increased more than sixfold during the past decade. More than 65% of cases occur in young men and women aged 15 to 29 years with the highest risk group in the 20- to 24-year age range. The high incidence of HPV infection in men has previously gone unrecognized because of the presence of small, subtle penile lesions, some of which are intraurethral. Examination of the penis with a colposcope or magnifying glass after washing with a dilute solution of 3% acetic acid will enhance clinical recognition. Spread of the HPV epidemic (estimated to affect some 2 million persons in the United States) needs to be controlled by effective treatment of the infected persons and their sexual partners.

In women, HPV frequently affects the cervix and has been linked to malignant progression, particularly when acting synergistically with other carcinogens. HPV-associated cervical lesions can be divided into three clinicopathologic categories: (1) typical (either flat or acuminate) condyloma with a low risk of malignant potential, (2) cervical intraepithelial neoplasia with koilocytosis with an ill-defined, low to high risk of malignant potential and (3) cervical intraepithelial neoplasia with nearly always a high risk of malignant progression. These categories of cervical lesions can be characterized by particular HPV types, by lesional nuclear DNA content and by cytohistologic morphology. Most condylomas contain HPV of types 6 and 11 and are polyploid. Cervical intraepithelial neoplasms, in contrast, generally contain HPV types 16, 18 and 31 and are aneuploid, regardless of their maturation or grade. The cytologic and histologic hallmark of HPV infection is koilocytosis, the presence of enlarged superficial squamous epithelial cells with a perinuclear clear space and hyperchromatic enlarged or pyknotic nuclei. Other, nonspecific findings associated with HPV include hyperkeratosis, dyskeratosis, epithelial hyperplasia, mild anisocytosis, binucleation, multinucleation and giant cell formation. In condylomas, anisocytosis and cytologic atypia are most prominent in intermediate and superficial cells, and, in general, basal polarity, basal organization and maturation are intact.

Aneuploid cervical intraepithelial neoplastic lesions, on the other hand, show cellular disorientation with loss of polarity, a crowded growth pattern, pleomorphism, increased nuclear-to-cytoplasmic ratio and chromatin clumping. Morphologically abnormal mitotic figures are identified with aneuploid cervical intraepithelial neoplasms, even in those HPV-associated lesions with prominent koilocytosis. The presence of abnormal mitotic figures and nuclear chromatin abnormalities in koilocytotic lesions of the cervix is the most reliable criterion for the diagnosis of cervical intraepithelial neoplasia and for differentiation from cervical condylomas. Therapeutic management of cervical condylomas and intraepithelial neoplasms should be based on lesion size and distribution as determined by colposcopy and is not a function of cytohistologic grade or classification.

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Dilated Cardiomyopathy—Subcellular Mechanisms of Disease

To clarify concepts about heart muscle disease, the World Health Organization and The International Society and Federation for Cardiology jointly defined cardiomyopathy as heart muscle disease of undetermined etiology. The uniform use of such classification and terminology may help clarify the multiple and complex disorders that have been included in a less restricted definition. Arguments still exist that suggest returning to the use of the term cardiomyopathy in its broadest sense, which could include the etiology of the heart muscle disease within the term. Irrespective of the classification or use of terminology, the common postmortem findings in such heart muscle disease are strikingly similar: characteristic cardiomegaly, globoid heart with left ventricular dilation and associated findings suggesting congestive heart failure.

Classifications alone do not help greatly in understanding the subcellular nature of intrinsic heart muscle disease. In similar ways, the cell biology of the failing myocardium is poorly understood. A growing body of evidence suggests progress in understanding some cell biologic and biochemical adaptive compensations in the cardiac myocytes under the influence of thyroid hormone excess or deficiency. In such conditions, alterations in thick filament function may relate closely to changes in quantity and distribution of cardiac myosin isoforms present in the cardiac myocytes.

Analogous evidence does not exist for relating myocardial contractile changes in dilated cardiomyopathy to the thick filament. An in vitro model of doxorubicin (Adriamycin) heart muscle disease has recently been created using cultured neonatal rat cardiac myocytes (CMC) in which CMC are treated with doxorubicin hydrochloride in vitro. Myocardial contractile protein synthesis was monitored with attention focused on actine, particularly α-actin, which is the isoform present in the cardiac thin microfilament.

A dose-dependent decrease in CMC protein synthesis and particularly of cardiac α-actin was seen in CMC administered micromolar doxorubicin. Lower doxorubicin concentrations did not cause this effect on cardiac α-actin synthesis. This in vitro observation may relate to the loss of contractility seen in doxorubicin-induced heart muscle disease in vivo. As sophisticated cell and molecular biologic techniques become available to cardiovascular research, the understanding of contractility defects of intrinsic heart muscle disease may rely less heavily on classification or morphologic observation and more heavily on the nature of the biochemical defect leading to the contractile failure.

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The Use of Fresh Frozen Plasma—Indications and Risks

Fresh frozen plasma is the liquid portion (200 to 250 ml) of one unit of whole blood that has been separated and frozen within six hours after donation. It contains the labile and stable components of the coagulation system, components of the complement and fibrinolytic systems, albumin, immunoglobulins and all other plasma proteins and nutrients. One ml of fresh frozen plasma contains about one unit of coagulation factor activity; each bag contains about 400 mg of fibrinogen.

During the past decade, the use of fresh frozen plasma has increased tenfold. Each year in the United States, 700,000 patients receive almost 2 million units of fresh frozen plasma, despite few established indications for its use. About 20,000 to 70,000 cases of viral hepatitis may be transmitted annually through its use. Additional risks include transmission of other infectious diseases, anaphylactoid or other allergic reactions, alloimmunization and volume overload.

In September 1984, the National Institutes of Health and the Food and Drug Administration sponsored a conference to examine the issues and increasing professional concerns about the indications, effectiveness and safety of the use of fresh frozen plasma. One conclusion was that 90% of its current use is inappropriate. Specifically, it was stressed that there is no justification for the use of fresh frozen plasma as a volume expander or as a nutritional source since safer alternative therapies exist. The following current clinical indications for use were recommended:

- Replacement of isolated factor deficiencies for factors II, V, VII, IX, X or XI when specific component therapy (factor concentrate) is neither available nor appropriate.
- Replacement of multiple coagulation factors in patients with liver disease or consumptive coagulopathies. The efficacy, however, of administering fresh frozen plasma to patients with coagulopathy related to liver disease has not been clearly defined.
- Reversal of warfarin sodium effect. Fresh frozen plasma replaces the vitamin K-dependent coagulation factors (II, VII, IX and X; proteins C and S) when anticoagulated patients are actively bleeding or require an emergency operation.
- Massive blood transfusion (greater than one blood volume within several hours). The use of fresh frozen plasma in cases of massive blood transfusion has greatly increased in the past decade, possibly due in part to a relative unavailability of whole blood. Hemorrhage in a massively transfused patient is caused more frequently by thrombocytopenia than by coagulation factor "wash-out." The use of plasma to reverse hemostatic disorders should be confined to those patients in whom factor deficiencies are presumed to be the principal or sole derangement. There is no evidence that its prophylactic use decreases transfusion requirements in multiply transfused patients who do not have documented coagulation defects.
- Use in antithrombin III deficiency.
- Therapy for thrombotic thrombocytopenic purpura.

In light of the recently published indications for and risks of the use of fresh frozen plasma, physicians should carefully evaluate their clinical orders for its transfusion.

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The Impact of Routine HTLV-III Antibody Testing of Blood and Plasma Donors on Public Health

NATIONAL INSTITUTES OF HEALTH

The appearance of acquired immunodeficiency syndrome (AIDS) has brought suffering and death to those who are afflicted and, at the same time, has posed daunting challenges to those who care for the sufferers, to biomedical scientists, and to those responsible for public health and public policy. Among these challenges is the protection of the nation's blood supply from contamination by the causative agent of AIDS—human immunodeficiency virus (previously referred to as human T-cell lymphotropic virus type III [HTLV-III]/lymphadenopathy-associated virus and subsequently referred to in this document as HIV in accordance with emerging and recommended usage). This challenge was met rapidly by the development of laboratory tests to detect the presence of antibody against the virus. The application of these tests makes it possible to determine whether the person has been infected by the virus at some time and, thus, to exclude persons from donating blood or to discard blood already donated. In the past 15 months, the widespread application of these tests along with self-deferral and removal of HIV-positive subjects from the pool of donors has sharply reduced the likelihood of the virus being spread by way of blood products.

Remarkable progress has recently been made in isolating the virus and in developing reasonably reliable tests for detecting its presence in blood by measuring the formation of antibodies against it. Mobilization of the whole scientific community, from government agencies and industry to the individual investigator, has brought about this progress, boding well for the eventual prevention of the disease. In fact, the prevention of post-transfusion AIDS is a typical example of the gains to be achieved by many years of supporting basic research.

However, the introduction of these tests has brought with it some problems. Questions can be raised about interpretation of the tests and their extension to purposes other than protection of the blood supply. As with almost every aspect of AIDS, the facts, opinions, and uncertainties of science are rapidly translated into public beliefs and social policy. Often, this translation has been inaccurate and incorrect. Policy has been made, or recommended, on the basis of an assumed scientific certitude that in fact may not exist. Conversely, scientifically sound information has been ignored or distorted by policymakers. Scientists have often failed to communicate their findings in ways that are useful for public policy.

The tests for evidence of infected blood are not yet optimally effective. There is still room for improved applications of the scientific method to identify methods with increased sensitivity, specificity, and predictive value. Because no test can be totally devoid of error, there must be continuing vigorous efforts to educate the public about who is a suitable donor of blood and to facilitate anonymous self-deferral at the time of blood donation.

To enhance understanding among scientists, those responsible for the health of individuals and of society, and the public at large, the National Heart, Lung, and Blood Institute of the National Institutes of Health (NIH) and the NIH Office of Medical Applications of Research sponsored this Consensus Development Conference on the Impact of Routine HTLV-III Antibody Testing of Blood and Plasma Donors on Public Health. Other sponsors of the conference were the Centers for Disease Control; the Food and Drug Administration; the Clinical Center, NIH; the National Institute of Allergy and Infectious Diseases, NIH; and the National Institute of Mental Health.

The conference brought together biomedical investigators, blood bank specialists, clinicians, consumers, and representatives of public interest groups. Following two days of presentations by medical experts and discussion by the audience, the consensus panel worked hard to interpret the scientific evidence. Comments and recommendations are organized according to the following questions:

1. What tests are currently being used? What are their performance characteristics?
2. What constitutes a positive test? How should a

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positive HIV antibody test result be interpreted? How should these tests be used?

3. How should positive test results be handled?

4. What are the psychosocial ramifications for blood donors of knowledge of a positive test result?

5. What impact has testing had on transfusion medicine?

6. What research directions should be pursued?

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1. What Tests Are Currently Being Used? What Are Their Performance Characteristics?—There are three approaches to detecting HIV infection. Listed in decreasing order of difficulty and expense, they are

1. Detection of the virus by culturing it.
2. Detection of antigens elaborated by the virus and present in blood.
3. Detection of HIV-specific antibodies that are produced by the infected person's immune system.

Two tests mainly support the entire current testing program. Both are of the third type. Enzyme-linked immunosorbent assay (ELISA) reacts to the presence of antibodies in the donor's blood, showing a more intense color as larger quantities of the antibodies are present in the serum. A positive reaction is recorded where the observed intensity exceeds a cutoff value set by the manufacturer of the test kit. If the cutoff value is set low, so that relatively faint specimens are recorded as positive, the chance of detecting HIV cases with low levels of antibody are increased. At the same time, such a low threshold increases proves the chance of recording as positive samples that do not contain antibodies against HIV, which can also produce color in the system. To protect the blood supply, it is prudent for a given test to set the threshold low and accept the increase in false-positives that must accompany that low threshold.

With a low threshold the ELISA test is quite sensitive; that is, truly infected persons are highly likely to give a positive reaction. But, uninfected persons—who are vastly more numerous—also occasionally give positive reactions to this test. This small fraction of uninfected donors produces many more of the positive reactions than arise from positive reactions of the few persons actually HIV infected. That is, the odds are great that any single ELISA-positive reading comes from an uninfected person. Furthermore, low positive values are often not reproducible; that is, a repeated, independent sample from a donor whose first test result was barely positive will likely turn up negative.

Current practice is that all donors are ELISA tested. If the test result is negative, the unit of blood is acceptable. If there is a positive reaction, two further ELISA tests are performed on the same unit. If both are negative, the unit is acceptable. If either is positive, the unit is classified as "repeatably reactive" and is destroyed.

In the nonprofit blood banking system, there is further testing of the blood of a repeatable reactor, aimed at clarifying the person's HIV status, which is still ambiguous since so many HIV false-positives occur among the ELISA repeatable reactors. The Western blot test is then applied. It, too, is an antibody detecting test, but it differs from the ELISA in several ways:

1. It gives information about particular antibodies among the several that HIV antigens may elicit; prominent among these are antibodies against p24 and gp41.
2. It uses electrophoresis and is thus more expensive and demanding of expertise than the ELISA.
3. It is less likely to give a false-positive or false-negative result.

If the specimen is Western blot positive, the donor is regarded as infected with HIV and notification of the donor is attempted. If the repeat reactor's Western blot test result is negative, the donor may be informed that

1. The blood is not, and will not be, usable.
2. The donor in all probability is not infected.

To protect the quality of the blood supply, it is essential to reduce the number of false-negatives to a minimum. However, false-negatives cannot be totally eliminated because some serum samples contain too little anti-HIV antibody to be detected; they come primarily from donors who have been infected very recently, typically during the first six weeks of infection, or from individuals who for one reason or another form antibody very slowly. It is essential to increase the sensitivity of methods for detecting anti-HIV antibody and to develop methods to detect and measure HIV antigens or infected T_4 cells.

Several versions of the ELISA test are on the market. They differ in their comparative sensitivity to the various antigens of HIV, and thus reflect somewhat different information about the antibodies in a given blood sample. They also presumably differ in sensitivity to sample constituents responsible for false-positive results. The cost-benefit ratio of simultaneously using ELISA tests from two different manufacturers on each sample to improve accuracy should be explored.

Several other methods of detecting anti-HIV antibodies are very useful for confirming and extending results obtained by the ELISA method, but are more time consuming. Western blotting is difficult to standardize, but staining of p24 together with gp41 is unequivocally positive. Correlation with intermediate and high ELISA values is excellent. Radioimmune precipitation and radioimmunoassay can be made both sensitive and specific by using very highly labeled antigens, but require skilled personnel and involve the use of radioactivity. Isolation of HIV is very difficult and time consuming and requires highly skilled personnel; it does not lend itself to analysis of large numbers of samples. It correlates highly with high ELISA values.

The most promising new approaches will be the development of fluorescent antibody techniques for detecting infected T4 lymphocytes and the development of techniques for detecting viral proteins, based either on antigen capture or on reverse transcriptase activation and synthesis of HIV DNA, which can then be detected with high sensitivity and specificity.

2. What Constitutes a Positive Test Result? How Should a Positive HIV Antibody Test Result Be Interpreted? How Should These Tests Be Used?—The virus thought to cause AIDS has been isolated, and its genome and gene products are largely characterized. Tests have been developed for the detection of virus, virus-coded proteins, and antibodies directed against these proteins. These developments have facilitated large-scale screening of blood and blood products for viral antibodies. Clearly, the tests in use have enhanced the safety of transfusion procedures.

Current procedures utilize an ELISA test for detecting antibodies against HIV as an initial screen. An additional test, the Western blot, is used to test serum samples found repeatably reactive in the ELISA test. Extensive experience has demonstrated that many samples that are repeatably reactive in the ELISA test do not react when tested by Western blot analysis. These discordant results indicate that many of the samples that are repeatably reactive in the ELISA test do not represent combinations with virus-specific proteins and often may not indicate the presence of an HIV infection.

Resolution of this problem is difficult because of limitations in currently available information. This is partly because investigators often use different methodologies, and licensed tests from different manufacturers probably differ in subtle yet possibly important ways. There are few published comparative analyses of the tests used in the field. Furthermore, Western blots have generally been carried out by personnel who are aware of the fact that the serum samples they are testing have reacted in the ELISA test. In addition, it often is not possible to estimate the specificity of these tests because ELISA-negative samples are not being routinely tested by Western blot. Consequently, there is still a need for rigorous studies to clarify many issues regarding interpretation of test results.

The most specific test for infectivity remains virus isolation; however, because of the complexity and difficulty of isolating HIV in cell culture, this is an impractical method for large-scale use. Some form of the ELISA test with enhanced sensitivity and specificity remains the most practical and feasible procedure for large-scale screening of the blood supply. Improved confirmatory methods should be developed that can be used in conjunction with such a test. Even with currently available tests, however, it is essential that confirmatory studies be performed without the laboratory personnel knowing the prior ELISA results. Specimens should be identified by a code number only, and a suitable number of ELISA-negative specimens should be included in each test run.

For purposes of notifying the donor, a confirmatory test such as the Western blot should be applied to resolve the actual HIV status because the repeated reaction may be caused by factors such as autoimmune or cell line-specific antibodies. Currently, however, blood banks are obliged to exclude serum samples that test repeatably reactive in the ELISA regardless of any confirmatory test results. Many of these almost certainly represent false-positive reactions. It is unfortunate that a considerable number of donors are functionally excluded from donation because of their questionable test status. Efforts should therefore be made to find ways to identify ELISA-positive individuals who are not infected so that their true serological status may be defined and their return to the blood donor pool expedited.

Available data indicate that the presence of virus precursors or antibodies in the blood reflects the continuing presence of HIV in the host. Thus, detection of such components represents a sign of continued infectivity of the blood. Like many other chronic viral infections, the period very shortly after exposure is often likely to be characterized by lack of antibody and by levels of virus proteins below the threshold of detection. In addition, biologic variation of both host and pathogen suggests that some chronically infected individuals do not synthesize virus-specific antibodies or make quantities of viral proteins that can be detected by assays currently in use. Nevertheless, such individuals are potentially infectious. Thus, while total elimination of infected blood from the national supply is not immediately feasible, it remains a desirable goal.

3. How Should Positive Test Results Be Handled?—"Positive" describes a repeatably reactive sample that is determined to contain antibody by an additional, more specific test, such as Western blot, radioimmunoprecipitation, and the like. Persons who have positive serum samples are termed "seropositive." A positive test result has the following significance as currently understood:

1. Such persons are infected with HIV.

2. Most persons infected with retroviruses such as HIV are infected for life.

3. All persons who are antibody positive for HIV, whether they are symptom free or ill, must be considered to be potentially infectious to others by sexual transmission, by sharing of drug injection equipment, by childbearing, or by donation of blood, semen, or organs.

4. Antibody positivity is not synonymous with having AIDS. However, by current estimate, as many as 35% of HIV antibody-positive persons may experience progression to AIDS over six to eight years.

5. We cannot precisely predict who among persons with antibody positivity will be ill or fatally ill in the future, and it is not possible at present to prevent such outcomes.

6. All antibody-positive persons should seek information and advice on how to protect their sexual contacts and future children from infection.

The panel believes that there is a clear ethical responsibility on the part of blood and plasma collection centers to notify individuals with repeatedly reactive blood in a sensitive, humane, and supportive manner. Consideration should be given to the donor's cultural and linguistic background. The need to maintain confidentiality of the information creates a duty on the part of blood collection centers to assume primary responsibility for notifying positive donors of their test results.

Notification should be followed by education. The panel believes that the central component to education is person-to-person interchange between the donor and the counselor. Additional techniques such as videotape presentations and printed materials may supplement, but not substitute for, personal interchange. Appropriate elements of a supportive counseling program for persons who are seropositive include education about the natural history of HIV infection and the meaning of a positive test result, advice on behavioral changes that will protect one's sexual partner(s) from infection, and referral to additional resources.

While blood collection centers will rarely have the trained personnel or assets to provide extensive and specialized counsel, we believe that they have a duty to cooperate with community agencies that can provide the necessary supportive services and to make effective referrals. These referrals would include the person's physician and other long-term counseling services, and such community agencies as local health departments, alternate test sites, AIDS service organizations, social service agencies, and others.

Confidentiality should be carefully and strictly maintained due to the sensitive nature of the information. Test results should be released to parties other than the patient only when there is a scientifically valid and legitimate need to know for public health purposes and, in principle, with the patient's specific consent.

Current practice in many centers is to enter the names of persons whose blood is repeatedly reactive but negative by Western blot into lists of deferred donors. We believe that it is inappropriate to enter a person's identity into such a list without his knowledge and without giving him the personal advantage of sharing that knowledge and its meaning. It is common practice to allow such individuals to donate again but to discard their blood without their knowledge. This practice should not continue; these donors have a right to be advised of their status.

Blood collection agencies currently maintain lists of deferred donors, onto which are entered the names of HIV antibody-positive donors. The agencies believe that such lists increase the likelihood that infectious units of blood will be screened out in the future should positive donors not self-defer. On the other hand, such lists are a potential source of loss of confidentiality for donors should their identity be inadvertently revealed. We believe that a balance of interests supports the entry of the names of those who are believed to be truly positive or whose status cannot be satisfactorily resolved, but only if such donors are informed initially that their name will be listed, if the list is very securely held, and if the list is used only for the limited purpose of protecting the quality of the blood supply. The actual utility of such lists should be regularly evaluated as technology improves.

Persons found to be seropositive may have a history of previous blood donations. For such persons, the question then arises about their past donations that have already been transfused into patients. In these cases, the blood bank has a serious responsibility to notify the hospital to which that blood was sent. It is the responsibility of the hospital, directly or through the patient's physician, to notify the patients of the possibility of having received seropositive blood and to educate them about the meaning of this. It is our opinion that, while the blood banks do not have the primary responsibility for the notification and counseling of recipients, they should, within their means, assist hospitals and physicians with accurate and effective information.

The repeatedly reactive donors (by ELISA) in the plasmapheresis setting cannot be characterized without additional testing as being either positive or negative for anti-HIV antibody. If the plasmapheresis industry is unwilling to test these donors further, the situation should be explained to the donor and the donor should be referred to an agency where such testing and pretest and posttest counseling are available.

4. What Are the Psychosocial Ramifications for Blood Donors of Knowledge of a Positive Test Result?—Everyone involved in blood and plasma collecting is aware of the potential psychosocial ramifications of the knowledge of a positive test result. Nevertheless, current data do not reveal the magnitude and nature of the short- and long-term psychosocial adjustment problems that seropositive donors and their sexual partners and family members experience. Possible outcomes include the effects on the individual's psychological and physical health, subsequent sexual behavior, lack of self-deferral behavior, and functioning in one's work and other social roles. Other research concerned with risk factors in health and illness has suggested that these outcomes will vary with the social and political climate of the community, the sociodemographic characteristics of the subpopulations at risk, and the individual's personality traits, social support system, and characteristic mode of coping.

Due to issues in confidentiality, the education and initial notification of donors of confirmed reactive and positive test results is the responsibility of plasma and blood collecting institutions and begins prior to blood donation. Anticipation of the donor's fear and distress is not a valid basis for not informing the donor. The content and manner in which the message is delivered may play a role in modifying the stress of being informed subsequent to a positive test result. In the notification procedure it is critical to differentiate between the ELISA test defined as repeatably reactive and the individual defined as seropositive based on additional confirmatory tests. It is also the responsibility of these centers to offer follow-up support and counseling through referral to the health care system.

There is a need for rigorous psychosocial research that will provide such data necessary to determine behavioral outcomes and to design and evaluate appropriate intervention strategies. The literature on the psychosocial outcomes for other life-threatening chronic conditions should be useful in this endeavor and will enhance research concerned with psychosocial ramifications for blood donors with positive test results.

5. What Impact Has Testing Had on Transfusion Medicine?—Human immunodeficiency virus testing has important implications for blood donors, patients, practicing physicians, blood banking operations, and manufacturers of blood products and devices.

Donors

The panel unanimously affirms that the primary means of preventing AIDS and protecting the public health is through the responsible behavior of individuals. Thus, the primary public health measure is education regarding what constitutes risky behavior and ways in which such behavior might be modified. With regard to safety of the blood supply, this responsible behavior consists of persons who are likely to be infected refraining from blood donation. This behavior must be encouraged in every reasonable way. It is our belief that punitive and threatening measures against groups that are at increased risk are counterproductive; they drive individuals away from responsible behavior and make education almost impossible.

Voluntary blood donors have the right to expect confidentiality of records of blood donation and anonymity with respect to the recipient of their blood. They should receive an explanation of tests to be performed and consequences of a positive test result and details of any lists on which their name may be entered.

Two widespread misconceptions regarding HIV infection exist among potential donors. The idea that blood donation places a donor at risk for AIDS is patently false. It is also incorrect that all infected donors will be detected by screening tests. Informational programs to dispel these ideas are needed.

Because of real or perceived social pressures, some persons at risk of transmitting HIV may feel compelled to donate blood. Procedures should be adopted by all blood banks to allow donors to indicate confidentially that their blood should not be transfused (self-deferral). Persons at risk for AIDS should be advised through programs of public education not to donate blood.

Alternative test sites should be available to allow anonymous access to testing without the need for voluntary blood donation.

Practicing Physicians

Blood utilization in the United States has declined significantly since 1982, the first such change in more than three decades. Much of this reduction appears to be the result of more judicious use of blood transfusion therapy by physicians. Preoperative autologous blood donation and intraoperative blood salvage have increased significantly and should be encouraged. These developments have reduced patient exposure to homologous blood and reflect good transfusion practice. Efforts should be made to increase the knowledge of practicing physicians about transfusion medicine and to make consultation readily available to them. Recipients should be adequately informed about the risks of blood transfusion. Effective peer review of transfusion practices should be maintained, and recording of the indications for blood transfusion in patient charts should be encouraged. All possible steps should be taken to avoid unnecessary blood transfusion. This is especially critical for neonates, who may be uniquely susceptible to HIV infection.

Blood Banks

There is uniform agreement that autologous blood is the safest form of transfusion therapy. Blood banks and blood centers should make this option available to all qualified healthy people with a scheduled elective operation, simplify the donation process to the extent possible, and inform physicians and patients about the advantages and merchandics of this approach. However, stockpiling of autologous blood without an imminent need should not be countenanced. In some areas, blood banks and blood centers have acceded to requests by individual patients for "directed donations," that is, donations by persons known to the prospective recipients. Although no evidence was presented to show that directed donations are any more or any less safe than donations from the general public for individual patients, the panel heard persuasive arguments against directed donations based on social and ethical considerations.

Transfusion medicine is emerging as a sophisticated individual discipline. Additional physicians well trained in this specialty are needed to meet educational needs, ensure appropriate transfusion practices, and encourage research and training programs.

Manufacturers of Blood Products and Devices

The plasma fractionation industry uses large pools of plasma for the preparation of certain lots of clotting factor concentrates. Despite highly sensitive tests for anti-HIV antibody used to screen individual units of plasma, final products may contain infected units not detected by these assays. Reasonably successful methods have been developed to inactivate virus in these products. Recent reports of HIV seroconversion in previously seronegative hemophiliacs receiving heat-treated factor VIII concentrates suggest the need to develop better procedures for removal or inactivation of virus. Production of certain clotting factors by recombinant DNA techniques and by monoclonal antibody methods is now in progress and should be encouraged.

Devices have been developed to salvage patients' blood during operations, following trauma and in other selected conditions. Recognizing the advantages of autologous blood, the panel recommends that industry continue to improve blood salvage devices.

6. What Research Directions Should Be Pursued?—It is remarkable that in the few years since AIDS was recognized, HIV has been characterized and tests for specific antibody have been developed and implemented for the protection of blood donors and transfusion recipients. However, the ELISA screening tests in current use fail to detect some infectious donors and yield positive reactions with many donors who are HIV negative. It is essential that more sensitive tests be developed to detect low levels of antibody. Highly specific confirmatory tests capable of distinguishing false-positive from true-positive reactions and that can be performed in a blood center are also required. In the early stage of HIV infection, virus may be present without antibody. In rare individuals with infection of longer duration, antibody levels may be too low to be detected with any test. Highly specific methods for detecting HIV in donor blood are available, but these are time-consuming, expensive, and lacking in sensitivity. Since direct detection of virus offers the most specific way of identifying donors who carry HIV, emphasis should be placed on the development of improved methods for detecting the HIV genome and virus-specific proteins in blood samples.

No definitive measures are yet available to predict which persons infected with HIV will develop AIDS, and much remains to be learned about modes of infection and the best ways of preventing the spread of HIV to personal contacts. Longitudinal studies of seropositive persons are needed to define outcomes in these individuals. Even in the absence of a cure for AIDS, better information on these issues would be invaluable to blood transfusion recipients and those carrying HIV.

Acquired immunodeficiency syndrome presents enormous challenges for psychosocial research. Persons in high-risk groups must be informed about the danger of transmitting HIV by transfusion and persuaded to comply with blood donor regulations. Effective methods of counsel and support for HIV-positive persons should be characterized and implemented. Considering that the next great threat from AIDS may come from heterosexual spread, means should be found to educate young, sexually active persons about the hazard of AIDS and the changes in behavior required to reduce the risk of contracting or transmitting this disease.

Since no methods of donor screening are likely to eliminate all risk of HIV transmission by blood, better methods of inactivating or removing HIV from blood products, especially those produced from plasma pooled from many donors, should be sought. Production of such products by recombinant DNA methods eventually should eliminate the risk of transmitting HIV and other infections with them.

Finally, and most obviously, the extensive efforts now under way to develop effective therapeutic agents for AIDS and methods for immunization against HIV should be sustained until these goals are achieved.

Conclusions

Remarkable progress has been made in applying the fruits of basic research to the development and universal application of tests for the detection of antibodies against HIV in blood collected for transfusion. Although test sensitivity is constantly improving, there is never a perfect test and exclusion of possibly infected donors remains important. A procedure should be adopted by all blood banks to allow donors to indicate confidentially that their blood should not be transfused (self-deferral).

As a result of the policy of minimizing the chances of positive blood slipping through the screen, false-positive test results will always occur. Extra efforts will be required to reassure donors and to salvage blood now discarded because of a false-positive reaction.

Confirmed positive test results mean that the donor is infected and has an unknown but real chance of developing AIDS. Disease will continue to be recognized in those who received infected blood before universal testing began and in the rare instance of transfusion of a blood product that for whatever reason falsely tested negative.

A policy of protection of the individual donor's privacy should be vigorously pursued; however, blood banks must be responsible for properly informing the individual and arranging for counseling. Much needs to be learned about the short- and long-term psychosocial adjustment problems of healthy people who are told they have an infection that may prove life threatening.

Every aspect of the problem requires continuing research. More sensitive tests that more specifically identify infectivity must be developed and tested in epidemiologically sound ways. Better methods of discouraging possibly infected donors and handling the psychosocial problems occurring in those with positive test results must be discovered through sound research projects.

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HMOs and PPOs: Pointers and Pitfalls

KENNETH E. LEE AND K. J. LEE, M.D.

Introduction

Health maintenance organizations and preferred provider organizations have become forces that patients, insurance companies, and above all, physicians can no longer ignore in today's rapidly changing world of health care delivery. New uproars, new challenges, new conflicts, new trends in the health care industry can usually be traced to some pre-paid health plan. Already, nearly one in ten Americans has enlisted with an HMO or PPO as his or her major payor for medical services; experts predict this may increase to 33% by the year 1995.[1] HMOs and PPOs have transformed the means by which consumers pay for their medical care and have shaken the traditional methods physicians use to deliver their medical expertise. Each day that health maintenance organizations gain more political and economic influence, it becomes all the more crucial for physicians and citizens to be aware of how they function and to know exactly what should be done to ensure one thing: that as they grow, HMOs and PPOs do not end up hurting those whom they were originally meant to help—the patients. The Federal government initially subsidized such "alternative delivery systems" to stabilize the rapidly increasing cost of health care through competition with traditional forms of third party reimbursement.

The Ideal and the Reality

At their best, pre-paid health plans can indeed do a great deal of good for society. The ideal HMO or PPO effectively keeps down the overall cost of medical care while still assuring top-quality medical treatment. The HMO or PPO, essentially a middle party that contracts with physicians and sells policies to patients, could potentially affect the cost of medical care in three ways. First, it could exert a downward force on physicians' fees and hospital costs through bargaining and negotiation in a newly competitive environment. Second, it could promote more efficient utilization of hospital and ancillary services through incentives that discourage unnecessary or inappropriate utilization. Third, it could cut administrative costs by conducting physicians' bookkeeping more cost-effectively than the physicians could themselves. If the HMO or PPO is able to achieve all three of these goals without jeopardizing the quality of medical care, then all of these savings can be passed on to patients in the form of competitive premiums and additional coverages.

Unfortunately, this ideal can crumble in reality. For many HMOs and PPOs, attempts at conducting bookkeeping with greater efficiency have been unsuccessful. Instead of streamlining the bookkeeping department, platoons of bookkeepers are generated: one tier for the doctor's normal bookkeeping, another tier to solve the problems caused by the HMOs or PPOs mismanaged reimbursement departments. For example, the physician who formerly monitored only overdue patient accounts must now also keep track of the different HMO fee schedules, overdue claims not paid by each HMO, the amount of "risk pool" withheld by each HMO, and fees owed by each HMO due to improperly processed claims—not to mention the jungle of confusing CPT codes. In effect, the bookkeeping burden has been multiplied instead of mitigated. This causes non-medical costs to rise—not fall—and patients and physicians are the ones who end up paying in the long run.

But there is another reason why pre-paid health plans can fall short of their goals. With the creation of the middle party comes the incentive for it to siphon off some of those savings for itself. If pre-paid health plan administrators see their business simply as a way to make money or to build an empire for themselves, then the entire purpose of the HMO and PPO has been defeated. Any saving of costs that has been achieved, instead of benefitting society, benefits the administrators or investors. This sort of activity creates a drain on the medical care system; the HMO or PPO becomes no more than a health care delivery black hole.

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What are HMOs and PPOs?

Health maintenance organizations work as brokers who arrange contracts between providers, patients, and physicians. An HMO offers its patient members nearly 100% coverage for most of their medical care without claims filing. Physicians file the claims and are reimbursed on an allowed fee-for-service basis or on a capitation basis. This allowed fee is usually substantially lower than the physician's customary fee. Additionally, HMOs withhold a percentage of the allowed fee until year end. This "risk pool" or a portion of it may or may not be returned to the physician, depending upon the financial health of the organization. In some cases, the physician may actually be liable for *more* than the value of his risk pool.

HMOs can operate under an "open-panel" system, a "closed-panel" system, or a variation of these two extremes. Under an "open-panel" system, the health maintenance organization contracts with physicians either individually or through an individual practice association (IPA). Any medically qualified physician, if he wishes, may join the HMO directly or through the IPA. Patients who purchase a policy from an HMO are restricted to consulting only those physicians who hold a contract with the HMO either directly or through the IPA. Under a "closed-panel" system, the HMO hires physicians on a salaried basis to serve its members, and no other physician may provide medical care for members of that HMO.

HMOs also contract with hospitals. Again, patients are restricted to using only those hospitals which are affiliated with that HMO. But HMOs can, if they wish, try to enlist as many hospitals as possible, providing its physician and patient members with as wide a choice as possible. It is also possible for an HMO to have its own hospital, thus severely limiting both the physicians' and patients' choices.

Health maintenance organizations are only slightly different from preferred provider organizations. Like an HMO, a PPO serves as an intermediary, negotiating contracts between the suppliers of medical services and the purchasers of medical care. PPOs can be sponsored by hospitals, insurance companies, or even third-party entrepreneurs. However, subscribers of PPOs—unlike the subscribers of HMOs—are not restricted to using only those physicians and hospitals which are affiliated with the HMO, although there are financial incentives not to go outside the "preferred provider panel." Originally, physicians and hospitals were also not at risk for losses incurred by the PPOs cost of services, whereas they are at risk with some of the newer PPOs and with HMOs due to the possibility of never receiving their withheld risk pool at the end of the year. Finally, PPOs are currently subject to fewer regulatory restrictions from HMOs, making it easier at the present moment to develop and build preferred provider organizations. It is for this reason that one may expect PPOs to grow faster than HMOs in both number and size during the coming decade.[2]

The difference between HMOs and PPOs is so slight from the physician's standpoint that it should be of little concern to the physician whether he is dealing with an HMO instead of a PPO or *vice versa*. The important differences between various prepaid health plans are found in the contract between the physician and the HMO or PPO. As time passes, the distinction between PPOs and HMOs may become even less.

Cutting costs—or cutting care?

For the purpose of best achieving the goal of passing on cost savings to patients, the health maintenance organization or preferred provider organization should operate in such a way that only a minimum percentage of the premium dollar goes to cover overhead and administration of the HMO or PPO; the rest goes to patient care. Non-profit HMOs may not operate at maximum efficiency. However, such may not be the case if the non-profit HMO has a wise Board of Directors and a proficient management team. For-profit HMOs have a tendency to be more efficient, but one has to be careful that there is no incentive to "skim-off" profits to managers or investors. Profits should be kept to a minimum, and the revenue from premiums should be used for patient services.

Some HMO leaders have argued that they need the sizeable and flexible infusion of cash and investment that can come from only a for-profit venture in order to sustain a large advertising campaign, commit a substantial capital investment, and take advantage of economies of scale. But advertising does not help patients by educating them; it is a technique to attract more subscribers. And if one HMO advertises, other HMOs will too. Advertising, then, is not in the best interests of the patients; it is in the best interests of the advertising firms. Advertising succeeds only in raising the cost of medical care. As for a large infusion of cash and investment, this may indeed be necessary in a capital-intensive industry to pay for large factories and machinery, but a properly administered HMO or PPO needs only modest offices and computer equipment. Thus, non-profit HMOs and PPOs are still probably the best way to serve the interests of the community.

In attempting to cut medical costs, some HMOs and PPOs can institute procedures that also cut the quality of medical care. Americans do want *cost-effective* medical care: top quality, accessible medical care without administrative and bureaucratic waste. But Americans do not want rationed, *cut-rate* medical care. We must not cut corners where the health of men, women, and children are concerned.

In trying to discourage unnecessary hospital stays, HMOs and PPOs may put limits on hospital utilization. Perhaps it is true that as soon as a patient is medically fit to leave the hospital, he should go home. But patients are human beings, and prepaid health plans should not be in the habit of expelling patients unwillingly from hospital beds through coercion of the physicians. At the same time, if the HMO were to pay for an unlimited number of hospital days, people could abuse the privilege and remain in the hospital much longer than necessary.

A compromise is a co-payment system, by which both HMOs and patients would shoulder the cost of hospital stays after the patient is medically fit to go home. The amount should not be enough to hurt patients, but be enough to serve as an incentive for patients to leave the hospital as soon as they are fit to do so. The idea of co-payment can also be extended imaginatively and with proper forethought to office visits and routine diagnostic tests. The HMO or PPO, again, would pay for most of the cost, but patients would be required to pay a small fee as an incentive not to take advantage of free but unnecessary office visits or diagnostic tests. Other alternatives are the appropriate use of intermediate care facilities, home care, and alternative transportation facilities.

Peer review: a means of cutting cost

Peer review attempts to discourage unnecessary utilization of health care facilities. In order for it to work, patient contracts should be clear, easy to understand, and should spell out exactly what the policy covers: the length of hospital stay for each diagnosis without complications, how much longer for each complication, and how much more patients must pay as part of a co-payment if they wish to stay in the hospital longer than the policy allows. The contract should spell out that just because the policy will pay for a fixed number of hospital days does not mean that the patient will be medically "well" or "cured" at the conclusion of those number of days. It means that if the patient has not fallen ill with the conditions listed in the contract to merit further covered hospital days, he will not be fully covered by his policy; there will be a specified amount of co-payment. The contract does not state that the patient is to be "well" or "cured" at the end of his prescribed covered hospital stay. It merely states that without the specific objective findings listed (such as temperature or bleeding) the policy does not cover further hospitalization. Had he developed the complication listed in his contract, he would not have been discharged, and a co-payment would not have been incurred. Patients should be told everything before they purchase the product, and the product should be fair for all patients.

Peer review for physicians is simple and vital. By definition, a peer review committee should consist of peers, so members of the committee should be elected by physician members. The peer review committee should be in charge of evaluating utilization to ensure that physician members are practicing proper, ethical, and cost-effective medicine.

The members of the committee should also be practicing physicians who have sensitivity to daily patient care as well as a clear understanding of the daily trials and tribulations of patient care. They should also have the continued understanding that they will have to follow the same policies they create for others to follow. It would not be fair to have non-practicing physicians on the peer review committee formulating policy for others but not having to follow it themselves. Full-time physicians or medical directors should therefore be considered representatives of the administration and *not* of the physicians.

Physicians on the committee must also be fully accountable to the physicians who elected them; a list of physicians on the peer review committee should be published and distributed to all physician members. Moreover, if there is a disagreement between physicians and the peer review committee, there should also be a hearing committee to resolve the conflict.

It is also essential that the peer review committee function as fairly as possible, giving physicians the same simple rights as any citizen would have in a court of law. It is not only in the physicians' and patients' interests that the prepaid health plans function fairly; it is in the HMOs and PPOs best interests as well. Most basically, physicians should be "innocent until proven guilty," as are all citizens in this country. Some HMOs and PPOs begin penalizing physicians by withholding payments before they have been evaluated by the peer review committee; this represents the opposite philosophy: "guilty until proven innocent." Under current labor laws, it is illegal for an employer to withhold an employee's salary because he has performed inadequately. Likewise, HMOs and PPOs should not have the right to withhold a physician's fee for a service he has already performed before a hearing by a review committee. Instead, the physician should be paid in a timely fashion for whatever service he did perform, and then appear before a review committee. If the committee finds his care inappropriate, then it would be legitimate for the HMO either to fine the physician or to withhold the amount owed from *future* fees.

Equally important, the peer review committee must consist of physicians from all specialties so that there is adequate broad-based input. All credentialing systems of this sort should also have certain rules and guidelines that apply to physicians of all specialties, but in addition have different "sub-rules" that apply to specific specialties to reflect intra-specialty peculiarities.

The HMO, the PPO, and the Physician

Some HMOs and PPOs, in attempting to attract physician members, will claim that they can broaden the physician's patient base. In actuality, HMOs and PPOs are really taking patients away and assigning them back to the same physicians at lower fee schedules. After all, a Connecticut physician is not going to start seeing new patients from Kansas; even with an HMO, he will continue to see patients from precisely his same patient base.

The health maintenance organization and preferred provider organization were meant to search out and implement ways to cut waste from the cost of medical care. A reasonable avenue to achieving this is a partnership among administrators, payors, physicians, and patients. To that end, the Board of Directors of any HMO or PPO should consist of adequate numbers of providers (physicians), consumers (patients), and payors (businessmen) to interact with the administration. Physicians are by no means meant to control HMOs and PPOs, but they must have meaningful input as equal partners.

Contracts between the individual physician and the HMO or PPO should not, therefore, consist of ambiguities and fine print qualifications. All penalties for both parties should be spelled out clearly, and a summary page of all the salient points should be included.

For example, physicians should be provided with the correct CPT (Current Proceedural Terminology) codes and corresponding fee schedule so that both parties understand how to cooperate and use the system to mutual benefit. In order to avoid confusion among the physicians and patients, all HMOs and PPOs should use the same CPT code for the same procedure. As new procedures arise, new CPT codes and fees should be formulated. When unusual procedures are performed, the HMO or PPO should not pay an arbitrary fee or not pay at all. For such rare or unusual cases, there should be a dialogue between the physician and the HMO or PPO to come up with an appropriate CPT code and fee, thus avoiding counterproductive blaming and finger-pointing.

In devising the fee schedule, HMOs and PPOs should work from a list of the true average fees for the community – not a fabricated list that is the "average fee" list in name only. An HMO or PPO should not create its own fee schedule and then call those fees the average fees for the community. If an HMO or PPO cannot afford to pay the true average fee, it should tell the physicians that it honestly cannot afford to pay the full average fee, instead of pretending that the amount they can afford to pay *is* the "average fee" for the community. Furthermore, the patients should be informed of contract limitations and restrictions; deception does nothing more than infuriate the public.

An example of an unfair clause which is sometimes buried in physician contracts is the right for prepaid health plans to seek reimbursement from its physician members if the HMO or PPO loses a lawsuit levelled by a subscriber. Is it fair for physicians to pay for an HMO's or PPO's liability? A physician should bear his own liability; an HMO or PPO should do the same. Moreover, the physician's own liability insurance usually does *not* cover the vicarious liability he incurs by signing such "hold harmless" clauses.

In the interest of treating physicians as partners, HMOs and PPOs could include in their physician contracts mechanisms for effecting automatic fee adjustments for factors such as inflation and malpractice insurance premiums. To encourage efficient and timely reimbursement of doctors, HMOs could agree to pay interest on late processing of bills. HMOs and PPOs could also try to reduce the administrative staff of the physician by instituting computer tie lines which would transfer funds much like banks have been doing for years. As soon as a patient is seen, the doctor could be reimbursed, thus promoting efficiency and contributing to lower medical costs.

A tactic that an HMO or PPO can use to control its physician members is the same tactic Alexander the Great used to build his empire: divide and conquer. An HMO is capable of diluting physician input through regionalization and pitting physicians against each other by exacerbating the importance of idiosyncracies and differences between specialties and regions. To avoid a lack of sufficient, effective input, local issues that are specific to a specialty or region should be decided in that setting. If competing local concerns have to be discussed and decided at a central, statewide board, those physicians affected should be represented at the board meeting and have voting rights. When drawing up fee schedules, HMOs sometimes give the entire physician community a budget and ask them to determine a maximum fee schedule among themselves. Not only does the HMO avoid the hard work of formulating fees, but it forces physicians into the difficult and perhaps illegal position of worrying about the fees of their colleagues in other specialties. Instead, the HMO should work diligently to derive the fees from a current database for each specialty separately, knowing how much it can afford to pay out to each specialty and in total.

By far the worst method of payment is the "capitated gatekeeper," by which a primary care physician is paid a sum of money per patient and can "spend" it any way he wishes. The primary care physician may then have an incentive not to refer the patient, or may refer him late in the clinical course at a stage involving higher risk, thereby jeopardizing the patient's health. This may be the most effective fashion of purely cutting costs, but it can cut the quality of medical care. The optimal level of patient care is no longer in the physician's best interests; the opposite is true. The old unethical practice of profiting by refering a patient (fee splitting) is resurrected as an equally unethical practice – profiting by *not* refering a patient.

Another payment device used to save medical costs is the noncapitated gatekeeper or "case manager." With this gatekeeper, all patients must first see a primary care physician for a particular illness. If the primary care physician deems it necessary for the patient to see a specialist, he refers that patient to a specialist. By creating the requirement for patients to see their primary care physician first, HMOs or PPOs hope that patients with minor problems which can be treated by a primary care physician will see them instead of the specialist, resulting in reduced medical care costs. HMOs also hope this will discourage patients from "shopping" for excessive second, third, or fourth opinions. Unfortunately, this sometimes represents an inconvenience for patients who no longer have the choice of going directly to their specialist even though the symptoms are obviously within a single specialty. Patients instead have to go out of their way to be seen by a primary care physician only to be referred to a specialist. Moreover, patients must get a new referral slip for each new problem. It is also possible that in the long run, this system may actually result in increased medical costs, because a patient with a serious illness, who would have seen a specialist first, must under the gatekeeper system first see a primary care physician and then be referred to the specialist, creating extra cost for the extra visit.

A compromise between the two extremes would be a system that combines the traditional gatekeeper with increased freedom of choice for the patient, resulting in a system which is "patient-friendly." If the patient sees a specialist instead of a primary-care physician first, the HMO should reimburse the specialist the amount of a primary-care physician's visit, and the patient should make a co-payment. This way, prepaid health plans would pay out the same amount in medical costs, patients would have freedom of choice, and because of the co-payment clause, there would be an incentive for patients not to go directly to specialists even though it may be more convenient.

The HMO and PPO: living up to the promise

In the final analysis, have health maintenance organizations and preferred provider organizations done any good for the health care system in this country? They have, for the first time, encouraged cooperation among businessmen, physicians, and patients alike. But not every HMO and PPO in this country has lived up to its promise; if HMOs and PPOs forget their purpose, they can deteriorate into merely special interest commercial enterprises attempting to seize and retain larger and larger portions of the health care delivery pie. In the practice of veterinary medicine, the veterinarian makes the diagnosis and must obtain the permission of the pet's owner before hospitalizing the pet or instituting any treatment. We hope that the practice of medicine does not deteriorate to that level at which the prepaid health plans view themselves as the *owners* of the patients, granting or withholding permission for hospitalization and treatment programs.[3]

It is, therefore, up to physicians to help HMOs and PPOs grow in the proper direction. And it is up to HMOs and PPOs to conduct business with fairness; physicians and patients deserve to be treated with openness, candor, honesty, and dignity. Only through the mutual trust of all parties concerned will the "medical cost crisis" ever be solved. Most physicians earn that trust every day of the week, every hour of the day and night, caring alike for patients who pay them well and for patients who cannot pay them at all.

HMOs and PPOs should be a mechanism by which employers and patients will pay only what it costs for optimal health care, without percentages being siphoned off to support unrelated corporate bureaucracies or to produce profits for corporate third party payers and their sales agents. HMOs and PPOs are *not* alternative delivery systems; they are alternative *payment* systems.

Only physicians can "deliver" health care, appropriately utilizing the resources of hospitals, laboratories, pharmacies, and other non-physician providers. In patient care, the bottom line is human life and health, compassion and caring.

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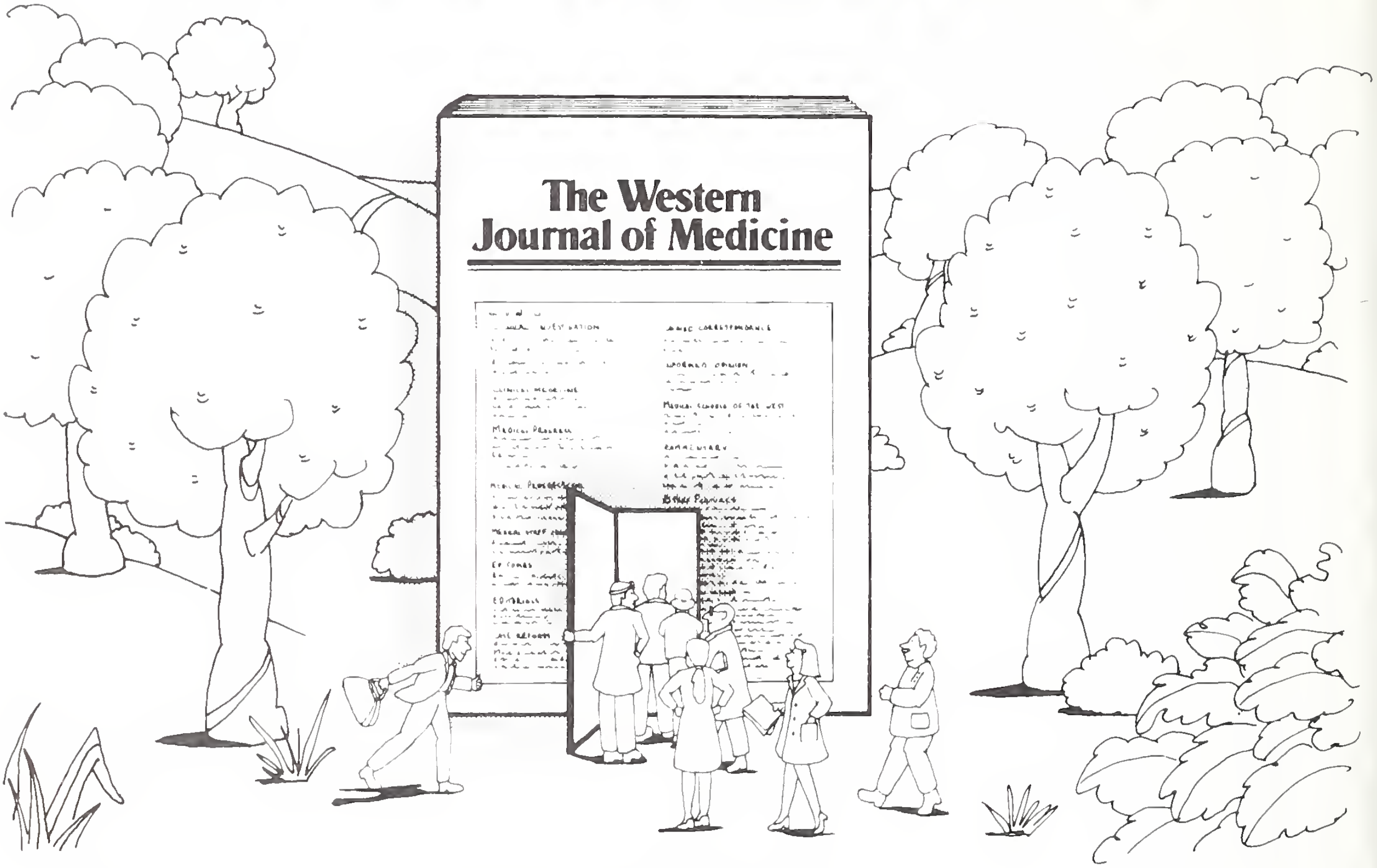
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DRG's, Myths and Facts

ROBERT L. MULLIN, M.D.

Introduction

Since October, 1984, Medicare has reimbursed hospitals by the Prospective Payment System (PPS) with a specific rate per Medicare admission based on the Diagnosis Related Groups (DRG's) system, developed at Yale University. The system is still being phased in and has a complex combination of DRG rates and hospital specific rates but eventually all hospitals will receive the same national rate modified only by regional wage indeces, rural or urban status and teaching status. This payment system applies only to care rendered in an acute care hospital and does not effect the physician reimbursement under Part B. This radical change from the long standing cost based Medicare payment method has evoked a great deal of literature in both lay and medical publications. Many of these articles have not presented a true picture of the situation mostly due to a poor or limited knowledge of the DRG's, PPS, or both. I would like to try and clarify some of the most prominent myths currently circulating.

Myth: The patient must leave the hospital because the DRG time has run out and Medicare will not pay for anymore care.

Fact: Medicare does not assign a specific length of time for each DRG. A trim point (specific number of days) is established for each DRG and the case becomes an outlier after that point. This does not automatically stop Medicare payment. On the contrary, if the continued stay meets the criteria for acute hospitalization, Medicare provides an extra per diem type payment for every medically necessary day.

Myth: All Medicare patients having a procedure appearing on the approved Medicare Ambulatory Surgery List must be done in an Ambulatory setting.

Fact: The medical condition of the patient is the major factor determining whether the case is suitable for an ambulatory setting or requires inpatient care.

Myth: Medicare PPS pressures physicians to discharge patients before they are ready and to withhold diagnostic and therapeutic procedures.

Fact: Medicare does not get involved in anyway with patients still in the hospital, nor does the Peer Review Organization (PRO). Any pressure comes from the hospital. In my experience, Connecticut hospitals have not unreasonably pressured the physician to discharge early or withhold necessary diagnostic or therapeutic procedures. Many other payors, however, bring a great deal of pressure on the physician, the hospital, and in some cases, even to the patient directly during their actual hospitalization. I am amazed that this gross intrusion on the physician's ability to render quality care is tolerated by both hospitals and physicians and that no criticism appears in print. Apparently we are so used to attacking government regulations, we fail to see what is going on around us.

Myth: When Medicare does not think an illness or procedure is worth very much the DRG weight is reduced.

Fact: The DRG weight is the ratio of the average total hospital charges for over eleven million Medicare discharges in FY84 (total dollar charges divided by the total number of Medicare discharges) and the average charges for each DRG (total dollar charges for all patients in the DRG divided by the total number of patients in the DRG). Therefore, the weights reflect the actual hospital charges for each group of cases.

Myth: Imposition of a Severity of illness measure would be beneficial to all hospitals.

Fact: PPS is a budget neutral system, ie. the total amount to be spent is predetermined by Medicare. An increase in rates in one area means a reduction in another area. Thus, if higher payment is to be made for "more severely ill cases" then lower payment will have to be made for "less severely ill cases." Imposition of a severity measure will increase payment for

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a small number of cases and reduce payment for many more. This will drain huge sums of money from the small community hospitals and pour most of this money into the major university teaching hospitals with the remainder to the large community teaching hospitals. Perhaps the results of a recent survey pointing out that the vast majority of hospitals in the country feel that they have a higher than average number of the most severely ill cases explains the popularity of the severity issue.

Conclusions

The primary problem is that the DRG's, and most of the other patient classification or severity systems are dependent on the International Classification of Diseases-9th Revision-Clinical Modification (ICD-9-CM) which is the coding system that all hospitals must use to code diagnoses and procedures. This system is woefully inadequate as a base for a patient classification system. It is based on the International Classification of Diseases (ICD) that was developed decades ago to classify causes of mortality and is not reflective of modern clinical practice. The procedure classification is too specific in some areas and too non-specific in others. For example, procedures on the eye are contained in twenty-three (23) pages and consist of two hundred and eighty-four (284) individual codes while procedures on the respiratory system (including the larynx, trachea, bronchus, lung, chest wall, pleura, mediastinum and diaphragm) are contained in nine (9) pages and consist of one hundred and nine (109) individual codes. One example of the problem is that the suture or repair of any artery in the body, from the digital artery of the fifth digit to the thoracic aorta, is coded to only one code. Efforts to revise ICD-9-CM have until very recently been met with considerable resistance. The Department of Health and Human Services has established an ICD-9-CM Coordination and Maintenance Committee and the first revisions are in place. They are scattered and not extremely helpful but it appears that a systematic approach to revision is underway. It is essential that the physician community become actively involved in this effort.

Fine tuning of the payment system for outliers would eliminate most of the perceived inequities due to "severity." Day outlier trim points should be set using a combination of statistical data and clinical validity and not the current geometric mean length of stay currently used to bring more cases into the average payment area. Currently cost outlier payment is not allowed if the case is also a day outlier. A fairer system would pay the higher of the day or cost outlier amount.

The Medicare PPS and the DRG's are, of course, not perfect. Instead of constantly attacking the system, efforts would be better spent to revise these areas where real problems exist.

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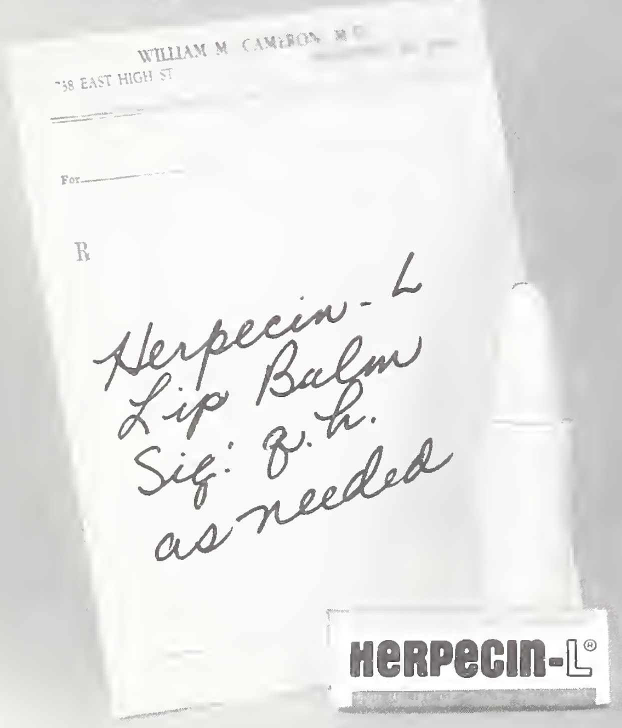

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Polygraph

AMA COUNCIL ON SCIENTIFIC AFFAIRS

The American Medical Association (AMA) Council on Scientific Affairs has reviewed the data on the validity and accuracy of polygraphy testing as it is applied today. The use of the control question technique in criminal cases is time honored and has seen much scientific study. It is established that classification of guilty can be made with 75% to 97% accuracy, but the rate of false-positives is often sufficiently high to preclude use of this test as the sole arbiter of guilt or innocence. This does not preclude using the polygraph test in criminal investigations as evidence or as another source of information to guide the investigation with full appreciation of the limitations in its use. Application of the polygraph in personnel screening, although gaining in popularity, has not been adequately validated. The few limited studies that have been performed suggest no greater accuracy for the types of testing done for this purpose than for the control question polygraph testing used in criminal cases. The effect of polygraph testing to deter theft and fraud associated with employment has never been measured, nor has its impact on employee morale and productivity been determined. Much more serious research needs to be done before the polygraph should be generally accepted for this purpose.

The polygraph is a combination of instruments that records a subject's blood pressure, pulse, respirations, and galvanic skin resistance while a series of questions are posed. In a pretest process, the examiner asks a series of questions to evaluate the voluntary subject (suspect), obtains an informed consent, derives necessary background information, and establishes the kind of relationship that facilitates the test by putting the subject at ease and stabilizing the parameters being measured. Finally, the formal questioning is begun. The subject is given a series of carefully formulated questions: the relevant questions dealing with the issue at hand, irrelevant questions, and control questions. The latter are designed to create the probability that the subject will lie or at least be unsure of the truth of his answer. By comparing the magnitude of responses to relevant and control questions with those to irrelevant questions, the examiner makes an interpretation on the truth, falsity, or inconclusive nature of each response. This is called the "control question technique."

In other applications (eg, federal security and preemployment testing), control questions, relevant/irrelevant questions, or the techniques of concealed information, guilty knowledge, and peak of tension tests are employed. In each of these last techniques, questions are targeted with a different intention than in the control question technique. Thus, although instrumentation is rather standard, it is the structuring and the substance of the questions, depending upon the purpose of the test, that require great expertise and that are central to the effectiveness of the tests. The control question technique has been used for criminal testing and has seen the greatest study.

These "lie detector" tests have been offered in court as evidence since the 1920s. However, in 1923 in the landmark case of *Frye vs United States* (293 F 1013 [DC Cir 1923]), it was stated that "the systolic blood pressure deception test has not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting expert testimony deduced from the discovery, developments, and experiments thus far made." Even after 60 years, this doctrine is still quoted widely in the courts. However, employers are increasing their use of the polygraph to screen prospective employees and workers to determine union sympathies and other attitudes. Even ten years ago, 250 000 to 400 000 polygraph tests were being given per year; in 1983, the American Civil Liberties Union estimated that 1 million tests a year were being performed. In 1982, there were an estimated 3000 polygraph examiners in the

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From the Council on Scientific Affairs, American Medical Association, Chicago.

Report G of the Council on Scientific Affairs, adopted by the House of Delegates of the American Medical Association at the 1984 Interim Meeting.

This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. This report reflects the views of scientific experts and reports in the scientific literature as of December 1984.

Reprint requests to Council on Scientific Affairs, American Medical Association, 535 N Dearborn St, Chicago, IL 60610 (William R. Hendee, PhD).

United States, and in the federal agencies alone, 23 000 polygraph tests have been performed.[1]

A National Security Decision Directive 84 (presidential directive, March 11, 1981) authorized executive agencies and departments to require that employees take a polygraph test in investigation of "leaks" of classified information to the media. On Oct 19, 1983, the Department of Justice announced that administration policy would also permit government-wide polygraph use for preemployment clearance and other screening of employees, and the Department of Defense has authorized its use in security screening of employees with access to highly sensitive material. Nevertheless, it is important to recognize that, even though such application may be helpful to the agency, the scientific validity underlying the polygraph test has not yet been established for these purposes.

Validity of Polygraph

There is a large amount of experimental psychological literature that examines many physiologic variables of subjects who, under experimental conditions, are asked about a mock crime they may have committed or about certain knowledge they may have been given and told to deny. This type of controlled analogue study may be very important in studying the reproducibility of test methods, examining the parameters most sensitive to deception, and generally defining the limits of the method; however, such studies can only provide a weak simulation of the real-life situation in which perhaps less scientifically motivated examiners are testing people who have been accused of serious crimes. Experienced examiners have claimed that a subject's behavioral cues can often enhance the likelihood of recognition of a deception. It has been shown in the experimentally controlled mock crime situation that an attentive examiner can detect such cues with a frequency that statistically is significantly higher in the untruthful group than in the truthful.

The difficulty in properly assessing the validity and reliability of polygraphy is partly because the "ground truth" is not always known, on the one hand, and the skill and training of the examiner may be at issue on the other. In one interesting study, field-trained polygraph examiners were asked to make blind judgments on polygraph records of 112 criminal suspects drawn from verified and unverified previous police investigations.[2] Half of the records had been verified (ie, ground truth was known through a confession); in the other half, the suspect had finally been judged truthful or deceptive by the original polygraph examiner. Cases were also divided between crimes against persons and crimes against property and between truthful and deceptive; thus, 14 sets of polygraph records were examined in each of eight categories. It is emphasized that only the records were examined; the ten examiners had no interaction with the subjects themselves.

In total, ten examiners made 1120 truth/deception judgments. Of these, 63.1% were correct, 1.2% were inconclusive, and 35.7% were wrong. There were no significant differences for verified or unverified records, for crimes against persons or property, or for evaluations by experienced and less experienced investigators. The examiners were asked to score the level of their confidence in the judgment made in each case. It was higher for deception than for truthful decisions. They also made more false-positive errors and fewer false-negative errors in records based on crimes against persons than on those against property, which suggests that crimes against persons may elicit a stronger physiologic reaction. In this study, true-positive judgments of deception averaged about 77% accurate, whereas true-negative judgments (against deception) were only 51% accurate.

The Office of Technology Assessment (OTA) review considered the outcome of validity measurements in ten such field studies that met their minimum criteria for scientific rigor: a reasonable basis for "ground truth," ie, a confession or the judicial outcome, was known. The range of values for the percentages of correct or incorrect decisions of guilt or innocence varied widely. In one recent study, 91.5% of guilty but only 29% of innocent subjects were correctly identified (52.9% false-positives and 17.6% inconclusive).[3] In a more recent study, 75.1% of guilty and 63% of innocent determinations were accurate, the remainder being false-positive guilty (25.0%) and innocent (37%) decisions.[4] Thus, it can be concluded that, although the polygraph can provide evidence for deception or honesty in a percentage of people that is statistically better than chance, there are enough false-positives and false-negatives to make many applications, perhaps even in criminal cases, of dubious value.

Personnel Screening and Public Policy Uses

It is obvious that the polygraph is not yet sufficiently accurate to establish the ultimate proof of guilt or innocence in a criminal trial. Its use as a condition of employment to establish national security clearance, determine union sympathies, or detect employees guilty of theft, breach of confidence, or other misconduct has become widespread; however, the few studies that have been done suggest that the techniques employed are no more accurate than the control question method discussed above. In fact, because the questioning deals with more minor issues and the consequence of failure is less serious than in a criminal case, it could be anticipated that the physiologic arousal of the sympathetic system might be less impressive and the deception of the examiner even easier than in a criminal case. Furthermore, the application of the polygraph test to a group, most of whom are certainly innocent, may frighten some into more careful and truthful answers but will also lead to a low level of predictability with a large number of false-positive results.

The erosion of employee morale and the risk of employer liability may not be worth the possible benefits of uncovering a disloyal employee. Furthermore, an unacceptable percentage of "innocent" persons may be labeled as "deceptive" in a polygraph screening situation in which most of those screened were truthful. It has been estimated that, even if the results of the polygraph testing were 95%

valid and the predictive value was 50%, in a screened population of 1000 in which 5% were guilty of some transgression, 47 of the 50 guilty people would be apprehended but 47 innocent people would also be labeled as guilty.[1] These calculations, although based on reasonable estimates from the experience in the field with criminal testing, may be too optimistic. Most potential employees are not under the same duress as a criminal on trial and, thus far, studies on the field techniques used in such applications are few and their scientific validity is no better than in the criminal investigation.

There have been no adequate field trials of the techniques now used for personnel screening, although analogue studies of the validity of some of the techniques used have been performed. The zone of comparison test and the modified general question test are based on the same premises and share the underlying rationale of the control question technique. Another format of questioning includes concealed information tests to detect whether the subject has information about a crime that only a guilty subject would have. It may take the form of a guilty knowledge test (GKT) or the peak of tension (POT) test.

In the GKT, there is a larger series of questions that may be of the multiple-choice type as opposed to "yes" and "no" or true and false, and they focus on specific details known only to the perpetrator of the guilty act. In the POT test, five to nine nearly identical questions were asked to which the subject is instructed to answer "no." The critical question is placed in the middle of the series, so that the physiologic response will build up to a peak at that point (if there is guilty knowledge) and then fall back down again as the questioning continues.

Analogue studies on students or other experimental subjects under controlled conditions have been reviewed.[1] In five studies of control question testing, the correct determination of guilt ranged from 60% to 87% and of innocence from 42% to 91%. Inconclusive results ranged from 5% to 44%, and false-negative (incorrect) results for the innocent ranged from 2% to 17% (average). In a review of five of the GKT analogue studies (which were not truly comparable in design), the accurate determination of guilt was 60% to 95% and of innocence was 80% to 100%. In these studies, an incorrect classification of guilty was made in 8% to 40% of subjects (average, 20%) and misclassification of the innocent as guilty averaged about 5%. Thus, it is fair to conclude that the concealed information tests are plagued, if perhaps less severely, with the same problem of false identification of innocent subjects.

The only analogue study that comes close to applying the control question technique tested military intelligence personnel in preemployment examinations.[5] Volunteers from the intelligence community were asked to respond to a series of questions on date and place of birth, educational history, employment, and residence information. Half of the subjects were told to give certain false information and were offered a reward if they could fool the examiner. Using a zone of comparison technique, the greatest control method, and the relevant/irrelevant technique, the identification of truthful subjects was accurate in 62% to 77% and incorrect in 15% to 23%; in 4% to 19%, the results were inconclusive. Thus, it can be concluded that a great variation in accuracy of classification and a substantial misclassification of truthful subjects occur regardless of the technique employed.

Factors Affecting Polygraph Validity

Because of the relatively high incidence of false-positive results, many students of polygraphy have tried to improve its accuracy by allowing for, or even eliminating, certain factors that have been shown to impact upon the test's validity. Others have studied countermeasures that might be successful in helping the suspect to defeat the test system. These factors may be broken down into operator characteristics, test subject characteristics, the setting for the test, and external influences. These have been reviewed at length in the OTA report; thus, only selected factors are listed here for the sake of brevity.

Operator Characteristics

Experience.—In one study, assessments made by experienced operators were shown to have a higher validity (91.4%) than those of interns being trained in the questioning technique (77.5%).[6]

Type of Training.—Objective scoring techniques (perhaps by computer) vs subjective analysis of responses need to be studied further to determine the most effective modality.

Selection of Polygraph Trainees.—This factor may play a role not yet identified.

Subject Characteristics

Gender.—Most testing has been done in males; there are few comparisons that might establish applicability of findings to females.

Psychopathy.—Guilty psychopaths may escape detection because they are not concerned about their misdeed; however, this has not been convincingly established by experimental or field trial.

Intelligence.—This factor may play a role in the subject's motivation to deceive or in enhancing the probability of detection, but requires further study.

Ethnic and Group Differences.—These may affect validity but have not been studied; however, the impact of ethnic biases on the subjective interpretations made by the examiner cannot be easily excluded.

Autonomic Lability.—The possibility that some individuals may be subject to easy autonomic arousal and others to late arousal seems very likely, but the extent to which this may mislead examiners requires further study. It appears that changes in ectodermal resistance may be less subject to individual variation than cardiorespiratory responses.

The Test Setting

Belief in the Test.—How much credence an individual being tested places on the polygraph method may determine his decision to try to "beat the machine."

Threat of Punishment.—The more certain that a guilty response will bring serious consequences, the more likely that the outcome is valid. This is the main hypothesis that is being exploited in each polygraph study and may explain some differences between field and analogue studies.

Instrumental Activity.—There is experimental evidence that subjects aware of being recorded have more intense responses to relevant questions, but not to control questions, than they did when they thought they were not being recorded.[7]

Test Location.—Although location of the test is generally felt to be very important, the impact upon validity of whether the test is administered in a special facility or in a room has not been determined.

Extraneous Factors

Physical Activity.—Tensing of muscles was shown to reduce the likelihood of detection from 75% to 10% in one experiment.[8] Other investigators have not always confirmed this, but most have shown that an inconclusive result is easily provoked by such a countermeasure.

Drugs.—Meprobamate has been shown to suppress autonomic activity and facilitate deception,[9] although studies utilizing diazepam or methylphenidate have not borne this out as a general finding for all antianxiety agents. β-Blockade has resulted in an increase in the rate of "inconclusive" tests, even though the overall error rate was not affected. Much more study of the effects of caffeine, alcohol, and psychoactive drugs is needed.

Hypnosis/Biofeedback.—In one isolated study, both hypnosis and biofeedback groups reduced detectability of deception (after training) to less than that in a control group.[10] However, other studies have suggested that hypnosis is not an effective countermeasure to prevent detection.

Mind-set.—Trained individuals who are familiar with the polygraph technique should be able to differentiate between relevant, irrelevant, and control questions. This would improve the possibility of "beating the polygraph test" through cognitive countermeasures. This possibility has not been adequately explored, although, in one preliminary report, subjects who have been coached and tested repeatedly are better able to avoid detection.[11]

Efforts to develop an objective computerized scoring system may have merit, but, in the opinion of most examiners, the subjective input of the examiner in the formulation of questions and in their application remains the critical point of the test as it is used today. Use of the control question technique has been well studied in criminal investigations, and its ability to detect guilt in crimes against person or property is fairly well defined. Nevertheless, false-positive and false-negative results suggest that one must always be left with some doubt in the final determination of guilt or innocence. When the application is changed to preemployment screening or a security clearance, there is substantial evidence that results will not be scientifically acceptable. This is partly because of the purposes of the test, which require significant variations in the questioning techniques used—zone of comparison, POT test, and GKT. These techniques have not been studied sufficiently in the field to determine the true incidence of recognition and predictability of the test results and the success of recommended countermeasures.

Summary

The polygraph instrument records a subject's blood pressure, pulse, respiration, and galvanic skin resistance. In a polygraph test, the variations in these parameters are recorded as the subject responds to a series of questions that are relevant or irrelevant to a specific issue or action under review or are control questions. When the relevant questions are focused on an alleged criminal act, this becomes the control question technique that is used in examination of a suspect criminal. It is well established that the polygraph can recognize guilty suspects with an accuracy (60% to 95%) that is better than chance. However, there is a significant rate of false-positive and false-negative determinations of deception so that the polygraph test alone can never be the sole arbiter of guilt or innocence. So far, this has been largely appreciated by the courts.

Criminal investigation has often benefited from polygraph usage because the investigator can focus on the incident in question, using it as the basis for selecting relevant and control questions in the application of the test, in the full knowledge that the detection of deception will not be absolutely accurate. Sometimes the simple threat of a "lie detector test" may facilitate the obtaining of a confession. At other times, the course of further investigation may be more easily plotted.

The use of the polygraph test in applications other than criminal investigation—for security clearance, preemployment screening, determination of paternity, periodic testing for thievery of disloyalty, cheating on examinations, and the like—has never been adequately studied. In those few studies of the validity of the testing technique that have been reported on noncriminal subjects (using modifications of control question technique), a wide range of false-positive and false-negative results, similar to that found in criminal investigations, has been reported and suggests too low a predictability for serious consideration of this application.

Aside from issues of invasion of privacy, self-incrimination, and impairment of personal dignity, it must be conceded that the polygraph test is not yet reliable enough to be the sole arbiter of guilt or innocence in a criminal trial. It has not been shown to be any more accurate when applied to personnel screening for governmental or private employers. Not only is there a significant false-positive rate, which would misclassify some innocent, truthful subjects as deceptive, but many countermeasures have been used—sometimes with reproducible success—to fool the polygraph examiner. The recent review by the OTA concluded "that there is only limited scientific evidence for establishing the validity of polygraph testing. Even where the evidence seems to indicate that polygraph testing detects deceptive subjects better than chance. . . significant error rates are possible, and examiner and examinee differences and the use of countermeasures may further affect validity."[1]

Conclusions and Recommendations

The Council offers the following conclusions:

1. In considering the scientific validity of polygraphy, one must consider the purpose of the test and the type of questioning technique employed. Each application must be examined individually.

2. Although the control question technique has been carefully studied in the context of a criminal investigation, where its limitations have been fairly well defined, the validity of this or other more commonly used techniques for personnel screening has not been adequately studied.

3. Those studies that may have some analogy to the use of the polygraph in personnel screening have demonstrated similar high levels of false-negative and false-positive classifications of innocent and guilty subjects that impair the use of the polygraph in criminal investigation.

4. The success of several countermeasures to prevent detection of deception has been legendary, yet serious scientific study of such countermeasures, such as tensing certain muscle groups, has been quite limited.

5. The possible savings in control of employee fraud and theft that might be accomplished by polygraph screening has not been examined in any scientifically valid study, nor has any investigator adequately examined the possible impact of polygraph screening on employee morale and productivity.

6. In screening tests applied to a large work population, predictability depends on the incidence of true-positive test results in that population but also on the false-positive and false-negative test results. This means that even with a test of 95% accuracy in a population containing few guilty subjects, an unacceptable number of truly negative (truthful) subjects can be misclassified as positive (deceptive).

The Council on Scientific Affairs, in view of these conclusions, makes the following recommendations:

1. Until polygraph testing and its scoring as currently used in personnel screening can be shown to be valid with a high level of predictability, the AMA should not support the use of the polygraph in industry or in federal agencies as a preemployment test.

2. The AMA should also recommend that, when any federal agencies believe that such polygraph screening tests are both ethically acceptable and administratively necessary for security clearance, much more research than is now planned on this specific application should be supported and conducted.

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Seven Poems

HENRY SCHNEIDERMAN, M.D.

A Doctor's Nos

No wine tonight, you are on-call.
No staying up 'til late in gorgeous mischief,
Or you'll have to pay, an early start you know.
No progress in your Greek, too much to read on lung disease,
No oil-paints but autopsy reports.
Too little time, and lessened ATP.

Let's exercise, it makes the juices flow.
Let's not, I'm beat,
My heart beyond my legs fatigued.

The bastard called me at my home for **That**?
No privacy, and no distinguishing
Between the earnest need and selfish want,
And mine a micropopulace.

Good days strive and struggle, beat the monster back.
For now.

No child's days.
No time to be a Dad?
No sense in that, no link to serving sufferers.
It seems we live to paperpush.
No full-Professor at such price, if that's the fault.
And sure no days of "Next!" if it's reduced to that.

No more: I'll heal the side of me that won't let go
I'll find a practice or a teaching post
That lets there be a little me at end of day.

Pre-dissection

For first-year students, noontime, optional,
"On Dealing with Anatomy."
Before you see or touch that body/former person/shell,
Discuss with veterans:
The second-years,
With therapist and a pathologist.
Speak your fears,
Let other people's feelings help your own, and skills.

So thirty women came, two males.
Congratulations, first-year men,
No wimps are here,
Let gals attend that seminar.
Cadaver's just a slab of exercise.
And I can cope,
Compartmentalize, suppress.
Let's not stir things up: just makes it worse.
There's certainly no relevance to dying ones
Nor to ourselves, our closing hearts.
Besides, tradition is
We've dealt so well with both.
Just get the facts.

Go into Law, or hauling sludge
No right to humancare which arid makes no fruit.

HENRY SCHNEIDERMAN, M.D., Assistant Professor of Medicine and Pathology, University of Connecticut School of Medicine, Farmington, CT; Teaching and Research Scholar, American College of Physicians.

Research Animal

Do mice have souls?
The blameless little mouse
Unknowing lives his days
Grows tumor or is "sacrificed."
Even—rarity extreme—
When useful knowledge grows,
How can we make it up to him
Whose breath, whose vision of the world and light
We take away, his only chance to be,
Who cannot give it back?
"It's just a mouse"
"We bred him"
"Could not live outside"
"To help some child"
Take away his life.
Yes, my child, God takes care of them
They scamper, nibble bits of cheese, their just
reward.

Forensic Seminar

I was a prostitute.
Terror had known me before:
I'd seen psychotic eyes, and murderous, but
God protector kept watch over me
Until the sordid night a person
Murdered me, cut off my breasts, my hands and head,
Set fire to the room to hide the crime.
Walks yet upon the earth, but how?
Police, strong-stomached, combed the scene.
Pathologist, a daddy, studied my remains,
And wondered, "What can make a person do this thing?"

The pictures teach us to collect the evidence.

A question from the floor:
The kind lieutenant says "We stick with it
To act for victims. They can't for themselves."

Create a God and heaven, please.
I need no less to make it right again.

Healer's Prayer

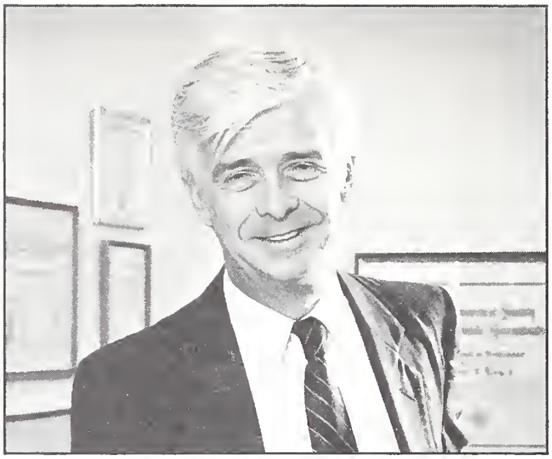
Lord God, King of the Universe:
Keep me aware that this toothless unspeaking old one
Has a soul, is
A person beloved by others
Dear-heart to a mother, a lover, a friend,
Comfort and source of a child,
Complex, no less human than I,
That in time for me too Death and Ill shall be real,
Lest divorce from the person exceed
What's required, and lapse
So mistaking the answers of parts, of disease
For the Life barely hinted;
Revere living things both in life and in death;
See in the sick one my brother-on-earth,
Not forget that the hospital stands
Interrupting the flightpaths ancestral of birds.

Prayer for the Mortally Ill in Winter

God, be kind in smaller ways
And let the snow be gone, sun drench
If not the lilac bloom within my time,
And I enough away from pain to see,
To feel its warmth upon my arm and face.

Prosector's Prayer

Lord God, King of the Universe:
Keep me aware that the flesh I prepare to dissect
Housed a soul, was
A person beloved by others
Dear-heart to a mother, a lover, a friend,
Comfort and source of a child,
Complex, no less human than I,
That in time for me too Death shall come,
Lest divorce from the person exceed
What's required, and lapse
So mistaking the answers of parts, of disease
For the Life barely hinted;
Revere living things both in life and in death;
See in the dead one my brother-on-earth, beyond help,
Not forget that the hospital stands
Interrupting the flightpaths ancestral of birds.



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The President's Page

Medical Courtesy Card: The Time is NOW!

The courtesy card program is now being implemented throughout the state and I urge all physicians that see Medicare patients to participate by accepting medicare assignment for those who present a Courtesy Card. It is a reasonable program from all points of view. The income levels are realistic and the method of obtaining the card is not demeaning.

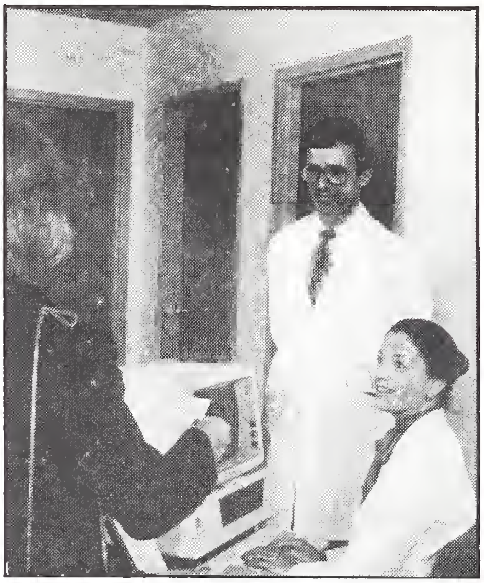
The Courtesy Card is available to seniors over 65 years of age, who earn less than $15,000 individually, or $18,000 as a family. Applications have already been sent to Senior Centers, Municipal Agents and to individual seniors who have requested them. Medical Society and Association staff people will review the application for eligibility, so that seniors should not feel embarrassed in any way. There has already been an overwhelming response from seniors and in merely one week's time, a New London County Senior Center has run out of forms *twice* and has asked for more.

In addition, letters have been sent to all of our member physicians with a sample application and a postcard to be returned to the Connecticut State Medical Society or your County Association indicating whether you are willing to participate in this most worthwhile program. If you have not already returned your postcard, please do so immediately. If you have misplaced it, call your County Association or CSMS at 865-0587.

A legislative task force on Medicare, of which I am a member, is currently considering the merits of our program. We must report to them the number of participant physicians as soon as possible. Opponents of our program have also tried to present "facts" to the Task Force. We must continue to show to the members our commitment to this program and, most importantly, our compassion by accepting medical courtesy cards.

Acceptance of the Courtesy Card may require taking a little more of our time with the seniors explaining the problems and solutions. It may require our office staffs to recognize that our senior patients have difficulty coping with paper work and forms and their taking some time to help the seniors out. We may feel frustrated with the shabby way our profession is treated by the government, but we can't afford to take it out on our Medicare patients. The Courtesy Card program is the first step in a campaign to show our Medicare patients that we do have their wellbeing at heart.

Joseph C. Czarsty, M.D.,
President



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Reflections on Medicine

From Chaos to Order?

ROBERT U. MASSEY, M.D.

Recently the economist, Eli Ginzberg, wrote of the present destabilization of health care and concluded, "Continued destabilization must be slowed and then reversed if we are not to undermine what has proved to be a highly satisfactory and effective system of care for most Americans."[1]

During a conference earlier this fall, held under the sponsorship of the Capital Area Health Consortium and the University of Connecticut Department of Community Medicine, and entitled "The Changing Roles of Trustees, Physicians, Nurses, and Administrators in a Competitive Environment," one of the speakers, a hospital director, described the numerous associations which his hospital had formed with IPAs, HMOs, PPOs, and local and national hospital chains, asserting that all of this was essential to retain and enhance "market share." After his presentation someone remarked privately that anything as ponderous as he had described and as complicated must surely collapse of its own weight.

Some of our first year students in a seminar devoted to examining the quality of medical care have encountered the Alice in Wonderland world of alternative delivery schemes, and of competition, cost containment, and corporate medicine. Theirs is a fresh view, and, because they are several years away from actual participation, they are curious and amused at the make-shift contraption, but they are also disturbed. Medical students are bright: it took no longer than half an hour of discussion for them to recognize the cross-purposes, contradictions, ethical pitfalls, and outright dissimulation inherent in most of these schemes.

I asked an administrator who was making plans for a new HMO-IPA what all these new ventures had to do with the quality of medical care. "Very little," he said. Nor did he think they would reduce the cost of care, or if they did, it would be at the expense of something valuable. "But it is chaos. It shakes things up," he added.

"My greatest concern is that we have been pursuing contradictory policies that are adding to our problems," wrote Ginzberg; "The competitive market is an opponent, not an ally, of cost containment," and he added, "Neither competition nor cost containment will ensure the maintenance of medical research and medical education, on which further advances in therapeutics depend." And, I suspect, neither will it improve the health of our nation nor of the world, nor the care of the poor, especially poor children, nor the treatment of the chronically ill, the disabled, and the elderly.

Our students did not seem pessimistic about all this, in spite of serious crepe-hanging by their older professional friends and relatives. Several had lived through experiences with grandparents who had been victims of the PRO and Medicare bureaucracies, others who had been badly treated by doctors in a hurry. They hoped that when the time came for them to practice their art they would have their principles in good working order; they also anticipated that something might happen to restore common sense to the whole affair before they began their professional work. Their hope was that our society, like science, would be self-correcting.

That hope is the best thing about a free society; we do not have to face the dreary prospect of one five year plan following another in conformity with some outworn nineteenth century ideology. Rather we can be reasonably sure that if we are caught up in a period of destabilization, but continue to worry about it and talk about it, a period of stability, perhaps moved up a notch, will almost certainly follow.

The corporate entrepreneurs, the bureaucrats, and the well-meaning administrators who now appear to be running things dismiss our talk of principles and ethics; they suspect we are covering up nothing but our economic self-interest. But patients are now beginning to worry that the quality of medical care is being sacrificed and access denied; they are the ones to recall us to our principles; they will demand, through their doctors, their political representatives, and their hospital boards of trustees, that the system be made to work to their advantage. We and they are natural allies.

ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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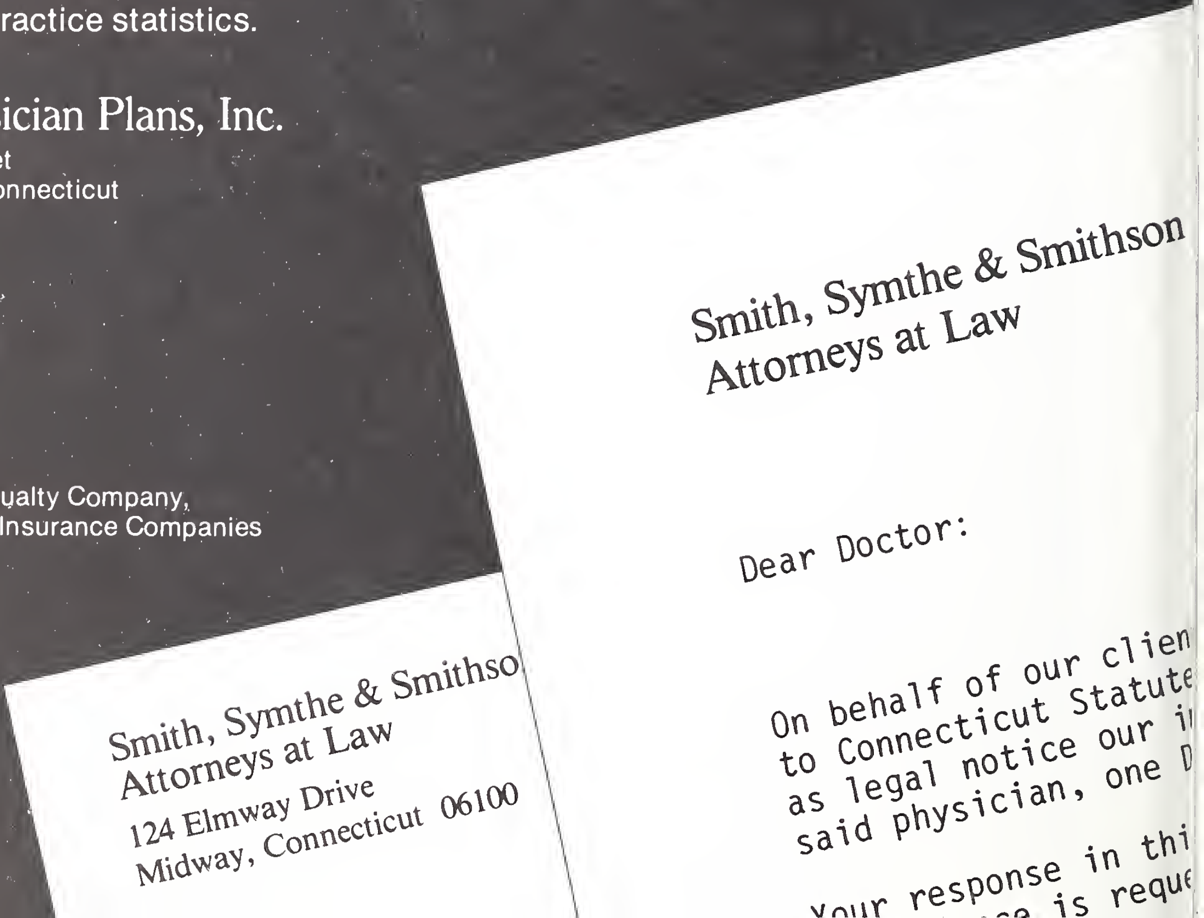

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Editorials

Pancreas Transplantation

Cure diabetes mellitus with a new pancreas? Why not? After all, kidneys, hearts, livers, and even lungs are now being successfully transplanted. With the new immunosuppressant drug cyclosporine, especially when used in combination with other immunosuppressive drugs, the results of transplanting those organs are most remarkable. For example, 95% of patients receiving cadaver kidney transplants at Hartford Hospital this year can expect to have their transplanted kidneys functioning a year later. All 18 heart transplant recipients at Hartford Hospital are currently alive and well. So why not apply the same technology to pancreas transplantation?

The first question to ask is why transplant the pancreas? The basic problem is that exogenous insulin administration alone does not prevent the development of microangiopathic complications in many patients. Conceptually, if a pancreas could be transplanted without unreasonable risk to the recipient, a pancreas transplant might "cure" many patients with diabetes mellitus. Despite the possibility that some patients will have recurrent diabetes mellitus in the transplanted pancreas due to the immunologic basis for some types of diabetes, many patients would probably not have the development of microangiopathic complications that lead to blindness and renal disease. This is supported by experimental studies in animals and the early results of successful transplants in humans.

If the serious complications of diabetes mellitus are due to frequent and marked imbalances in glucose homeostasis, and there is evidence that they are, then a properly functioning pancreas transplant could prevent those complications if it were performed at an early stage in the disease. An insulin pump and a blood glucose sensor could also achieve good glucose homeostasis, but that technology has yet to be perfected.

But pancreas transplants have also not yet been perfected. Several technical problems remain, including frequent vessel thrombosis, management of the pancreatic duct, difficulty in diagnosing rejection activity, and problems with even short term preservation. The paper on experimental pancreas transplantation which appears in this issue of *Connecticut Medicine* reports on attempts to improve preservation of the pancreas. The investigators found that the addition of colloid was an important consideration. More recent work from the University of Wisconsin (presented at the International Meeting of the Transplantation Society in Helsinki, Finland, in August 1986) indicates that the addition of low molecular weight hetastarch to preservation solutions will permit pancreas preservation equivalent to that currently possible for kidney transplantation. This will make possible more distant procurement of cadaver pancreases, and also probably decrease posttransplant pancreatic dysfunction due to poor preservation.

Other important advances in pancreas transplantation were reported at the Helsinki meeting. Vessel thrombosis was lessened by using prophylactic intravenous dextran, and the pancreatic duct seemed to be best managed by anastomosing it along with a small segment of duodenum to the recipient's bladder, thereby permitting allograft rejection episodes to be more easily diagnosed by measuring urinary amylase. The use of cyclosporine, especially when used in combination with other immunosuppressive drugs, along with refinements in surgical techniques, has increased one year graft survival from 30% commonly

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reported two years ago to an average of 50%. Some centers reported success as high as 70% one year graft survival, along with very little mortality. Myocardial infarction was a leading cause of death in some reports, indicating the need for very careful pretransplant patient evaluation.

Despite those important advances, the danger of long term immunosuppression, at least as we know it today, remains the critical issue when considering pancreas transplantation. Certainly for patients needing a heart or liver transplant, there is little choice. Without a successful heart or liver transplant, along with the needed immunosuppression, the patients have no hope for survival beyond a few months. Such is not the case for patients with diabetes mellitus. Insulin administration, despite its shortcomings, is preferable to the risks of current immunosuppressive drugs for most patients.

Yet many patients with diabetes mellitus are already receiving immunosuppression because of a kidney transplant. At many transplant centers, about 30% of the kidney transplants are for patients with end stage diabetic nephropathy. These are the patients currently being given pancreas transplants, providing that cardiac and generalized vascular disease has not progressed too far. In a few patients, having received both kidney and pancreas transplants, there have been no microvascular changes in the kidney transplant which would have occurred without the successful pancreas transplant. Diabetic retinopathy may not be as favorably affected, although the follow-up period is still relatively short.

Diabetics with successful kidney transplants have shown that immunosuppression is not inevitably a dangerous therapy. Many patients have been entirely free of side effects from immunosuppression. For example, one of our young patients with advanced diabetes mellitus received a kidney transplant 12 years ago. She continues to have excellent renal function and has not had any problems due to immunosuppression. Interestingly, her eyesight has remained stable since the kidney transplant.

Work has also progressed along another line of investigation, hopefully to cure patients with diabetes mellitus—isolated pancreatic islet cell transplantation. Studies in animals have been successful, even in primates. Unfortunately, long term success in human beings has not yet been reported. As with whole organ or segmental pancreas transplantation, there are several technical and immunologic problems which need a satisfactory resolution.

Given the remarkable advances in solid organ transplantation in the past few years, there is little reason to doubt that frequently successful and "low risk" pancreas transplantation will occur in the near future. Methods to increase graft acceptance without the occasional serious problems of chemical immunosuppression would be a very important development, especially for the diabetic patient where the risks of immunosuppression must be less than the risks of developing microangiopathic complications while on exogenous insulin administration. Despite the problems, pancreas transplantation is presently emerging from the experimental phase into the clinical application phase.

Robert T. Schweizer, M.D.
Chief of Transplantation Service, Hartford Hospital
Professor of Surgery, University of Connecticut School of Medicine

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A Vital Call for Physician Cooperation

In barely four years since it was first identified and named, AIDS—Acquired Immunodeficiency Syndrome—has become one of the most serious epidemics this country has ever seen. Without exaggeration, it can be said that AIDS threatens to become the major international lethal pandemic of the 20th century.

More than 20,000 cases have been found in this country; thousands more around the world. More than half of those who have contracted it have died. Estimates by medical and scientific experts who are studying AIDS are that probably two million people in the United States have already been infected with the virus, HTLV-III, now called HIV. The Centers for Disease Control predicts 274,000 cases of AIDS by the year 1991, of which about half will be fatal. And the CDC says its predictions may actually underestimate the situation.

Doctors across the country are being asked to cooperate in bringing accurate information about the disease to their patients and to the public at large. They are also being asked to cooperate in another pressing effort: notifying their patients who have received blood, plasma or platelets from sources that could have been tainted with the virus long before the blood banks had an available test for HIV among their donors.

The American Red Cross, the American Association of Blood Banks and the Council of Community Blood Centers are working together on a look back program, checking previous donation records of all would-be donors who now test positive for HIV. If it is found that such a person has donated before (an estimated 85 percent of the 12 million annual blood donations are from previous donors), all patients who have received the possibly contaminated blood or blood products will be identified, and hospitals or other institutions where the transfusions were given will be notified. They, in turn, will be asked to notify you, if one of your patients was involved.

Your first responsibility is to notify the patient that, although the odds are very slim, he or she might have been exposed to the virus. You should then refer the patient to a local testing center.

The look back program has been designed in a way that will maximize the chance of finding those few persons who may have been infected (and can possibly spread the virus), while at the same time, only inducing anxiety in a small number of persons. While we are distressed at the emotional impact this outreach can have, we feel this is a vital way we, as individuals, can actively curb the spread of AIDS in our communities.

Joseph C. Czarsty, M.D.
President, CSMS

Fashions in Disease

Sometimes it is impossible to account for all the changes in the patterns of disease in society. Often our changing interests have something to do with the rise and fall of this or that diagnosis; at other times diseases do fade away, as rheumatic fever has seemed to do. Recently this old clinical entity has been making a modest come back; even so, few medical students and residents will ever hear a diastolic rumble or see a child with acute rheumatic fever. An article which appeared 40 years ago in this Journal reminds us of this ancient enemy: [1]

"It is estimated that there are each year in the United States between 200,000 and 260,000 cases of rheumatic heart disease with an estimated rate of 1,500; 2,000 new cases yearly; and annually 30,000 to 60,000 deaths resulting from this disease. It is the commonest cause of death between the ages of five and nineteen and the second commonest cause in the age group nineteen-twenty-four. The average duration of life from the initial attack is fifteen years, and the life span of those patients with rheumatic fever and rheumatic heart disease is given as 36.5 years as compared to fifty-five years for the general population. About seventy-five years per cent of all rheumatic fever cases developed chronic deforming valvar diseases. After a period of ten years following the first attack, a period given as the average time interval from the attack to the appearance of cardiac insufficiency, out of a thousand cases it was found that 439, or less than one half, followed normal activities. About one-third, or 344, had impaired activities ranging from slight to moderate, and to marked degrees, and about one-fifth (203) were dead. As compared to six other common infectious diseases a New York City Health Department report a few years ago showed that there are 1,105 deaths from rheumatic fever and heart disease as compared to 105 from whooping cough, meningitis—53, measles 42, diphtheria 26, scarlet fever 17, and 4 from infantile paralysis.

"It is remarkable how we have had so much publicity, drives for funds and interest shown for infantile paralysis, and so comparatively little for the much more serious and fatal disease, rheumatic fever."

REFERENCE

1. Prout EB. Rheumatic Heart Disease. Conn State Med Jour 1947, 11:98-100.

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

CHECKING OUT LICENSURE BY CERTIFICATION

To the Editor: Am I the only physician who is annoyed by the new requirement that we must supply a bank certified check, rather than a personal check, to pay for the state license? This on the face of it appears to be the worst type of bureaucratic nonsense. Should some forgetful or dishonest person send in a bad check, why is it so difficult for the vast state administrative apparatus to either remind the culprit or to nullify the license? Meanwhile the rest of us are condemned to an extra visit to the bank and an extra charge, for no good reason. I think the Connecticut State Medical Society should protest this imposition, if they have not already done so.

Roy N. Barnett, M.D.
Westport, CT

The above letter was referred to Mr. Robert J. Brunell of the CSMS Staff who offers the following reply:

To the Editor: As a matter of fact, CSMS has checked into this "new requirement" since complaints first started arriving in September. It seemed odd to us that anyone can renew a driver's license simply by writing a check, but not a physician renewing a medical license.

According to personnel at the State's Bureau of Medical Licensure, the "requirement" has been stated on the renewal form for the past three years but not enforced. It has only been noticed by most doctors since the form was redesigned this year. The Bureau is now giving consideration to dropping the requirement in a furture version of the form. Meanwhile, the Bureau does not return personal checks to physicians, but it is accepting and processing them as usual. Of course, renewal will be delayed for those whose checks do not clear.

Robert J. Brunell
Assistant Executive Director
Connecticut State Medical Society

Call to Contributors

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult INFORMATION FOR AUTHORS. This material may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:
Robert U. Massey, M.D., *Editor*
Connecticut Medicine
160 St. Ronan Street
New Haven, Connecticut 06511
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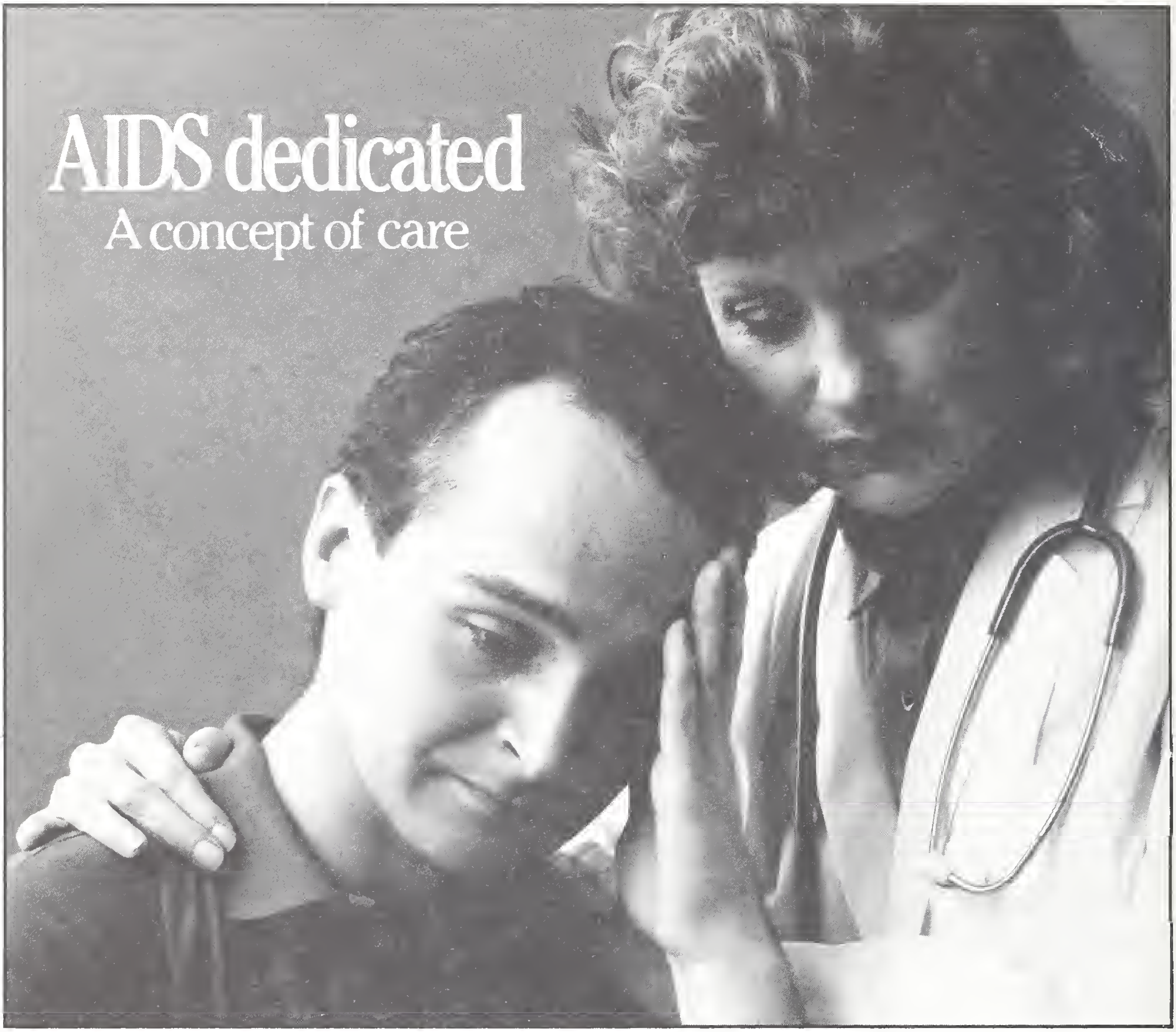

Photography by Ken Nahoum

AIDS is a complex disease, assaulting the psyche as well as the body. The Spellman Center for the Treatment of Persons With AIDS treats both. A comprehensive medical facility, Spellman is devoted to the care of those suffering from Acquired Immune Deficiency Syndrome.

Respect for individual dignity guides the Spellman program. Staffed by trained personnel dedicated to working with AIDS patients, the Center includes family and friends in the management of the patient's health crisis. Spellman also operates a 24-hour information hotline at 1-800-433-AIDS.

For criteria on admission and referrals, please contact the Medical Director, at 1-212-307-0735. Spellman is a division of St. Clare's Hospital and Health Center, designated the first AIDS treatment center by New York State.

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FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, CT 06511 Telephone 865-0587

Timothy B. Norbeck, *Executive Director*
Josephine P. Lindquist, *Associate Executive Director*

Raymond T. Sullivan, Jr.
Assistant Executive Director
Public Affairs

Robert J. Brunell
Assistant Executive Director
Scientific Activities

Shelley A. Marcus
Director of
Government Relations

Council Meeting

Thursday, August 28, 1986

Attendance

Present in addition to the Vice Chairman, Dr. M.S. Eslami were: Drs. Beck, Bonner, Czarsty, Dardick, Finn, Fox, Freedman, Friedberg, James, Kamens, McDonnell, O'Brien, Orphanos, Petrie, Ragusa, Robbins, Sweet, Welch, Wetstone, Zanker and Zlotsky.

Also present: Dr. Whalen, Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Sullivan, Mr. Staples, Ms. Marcus, Mr. Tomat, Mr. Freberg and Mr. Coffey.

Absent were: Drs. Abbot, Ahamed, Ahrens, Bobruff, Canzonetti, Reyelt, Jr., Rose, Sadowski, Schwartz, Sullivan, Jr., Van Syckle, Villa and Waldron.

Report of the President

Dr. Czarsty discussed the need for increased participation in COMPAC, above the current 16% level of CSMS membership. He mentioned that increased political activity was essential to protect our allies in the General Assembly, and preserve the tort reform gains made during the 1986 session.

Dr. Czarsty reported that his service on the Ad Hoc Committee To Study Medicare Assignment was an "eye-opener." He mentioned that Shelley Marcus and Cam Staples had presented testimony in favor of the Medical Courtesy Card Program, and that the United Seniors in Action (U.S.A.) had testified against it. Dr. Czarsty noted that the U.S.A. group was advocating mandatory Medicare assignment, similar to recent legislation passed in Massachusetts.

Dr. Czarsty presented a letter received from Dr. John D. Watson, Jr., President of the Medical Association of Georgia, concerning the Department of Defense's (DOD) plan to restructure the CHAMPUS program. The letter discussed the formation of The Alliance of State Physician Networks (ASPN) which was established by fourteen "Southern Tier State Medical Associations" to formulate a coordinated response to DOD's expected issuance of a Request For Proposal (RFP) later this year. ASPN invited all other State Medical Associations to join the Alliance and attend its next meeting on September 3, 1986.

The Council VOTED to send a representative to the upcoming Alliance meeting as an observer.

Dr. Czarsty also presented correspondence from The Department of Government and Community Affairs at Yale University, seeking an endorsement from CSMS for a federal grant to develop a pilot health care program aimed at New Haven's minority youth. The Council VOTED to table the request until a representative could be present to discuss the proposed grant.

Dr. Czarsty recommended that the Council nominate Guy W. Van Syckle, M.D. for a position on the AMA Council on Long Range Planning and Development. He read a letter to that effect, which the Council VOTED to approve and send to the AMA.

Following the report of the President, the following comments were made: Dr. James proposed the nomination of Edward Kamens, M.D. to the AMA Council on Medical Services. Dr. Kamens expressed his concern that his nomination might diminish Dr. Van Syckle's chances for success, and accepted the nomination with the understanding that he could withdraw at any time. The Council VOTED to approve Dr. Kamen's nomination.

Dr. Stewart Petrie urged members of the Council to help increase participation in COMPAC. Noting the pressure from senior organizations for Mandatory Medicare Assignment legislation, he encouraged greater political action to help prevent such occurrences. It was also noted that re-insurance for CMIC would probably not be available if the changes in tort reform were not enacted by the Connecticut legislature.

Report of the Executive Director

Tim Norbeck mentioned that the Medical Courtesy Card program was beginning on October 1st throughout Connecticut, and that plans were underway for a widespread publicity campaign. He pointed out that (U.S.A) United Seniors for Action had distorted the Courtesy Card program in its literature, and CSMS press efforts would be designed to clear up any misrepresentation.

Concerning tort reform, Mr. Norbeck mentioned that the Trial Lawyers Association will do everything they can to repeal the recent tort reform legislation.

Mr. Norbeck also reported on his participation as a member of a consulting team which surveyed the Rhode Island Medical Society physician leadership and staff. The RIMS has experienced considerable difficulties in the legislative arena, coupled with rapidly escalating malpractice insurance rates and dictates from their Blues plans.

CSMS IPA/HMO Update

Dr. Whalen reported on the development of the IPA/HMO project. He explained that although the name CHIP (Connecticut Health Insurance Plan) had been agreed upon by The Steering Committee, recent revelations about similar acronyms in surrounding states would force the Committee to pursue other names.

The IPA/HMO Development Budget approved The Steering Committee was distributed with the agenda. It totals $2,065,942 and includes projected advertising and MIS costs. The draft of the development contract is under review by separate IPA counsel.

Dr. Whalen outlined the HMO development process, complete with detailed timeframes for each task. He explained that the development was proceeding on schedule and mentioned that discussions with PHS were continuing, and that a meeting with PHS representatives was scheduled for that evening. Meetings were scheduled in the near future with representatives from the VHA and The N.E. Hospital Network. Dr. Whalen raised the question concerning the two hundred salaried physicians from the University of Connecticut who were not members of CSMS. He explained that a compromise proposal would be forthcoming from the University concerning the issue of CSMS and County dues for these physicians. The Council VOTED to reaffirm its opinion that all members of the IPA should be members of the State and County Medical Associations.

Dr. Orphanos raised for discussion the process by which six CSMS-IPA Directors shall be elected by the Connecticut State Medical Society. Discussion concerned whether the IPA Bylaws should include specific procedures for the CSMS Council and House of Delegates to nominate and elect the six directors. After extensive consideration, the Council VOTED to table the selection issue until the final draft of IPA Bylaws were rewritten incorporating the input from the Council.

Attorney Barry Scheur, Project Manager, received clarification from the Council that the IPA Bylaws, as submitted with the license application, will simply state that the six HMO Directors will be elected by The Connecticut State Medical Society with specialty and geographic consideration. A motion that the Council elect the HMO Directors and submit the names to the HOD for final approval was tabled.

CT Peer Review Organization

A communication was received from the Chairman of the CPRO Nominating Committee requesting CSMS to submit nominees for an opening in the directorship of CPRO. The term of Dr. W.A. Whalen expires, however, it is to be noted that Dr. Whalen is eligible for re-election. Other CSMS members serving as directors are Drs. Canzonetti, Doctor and Eslami.

The Council VOTED to approve Dr. Whalen's reappointment for three more years.

Task Force On The Prevention of Prescription Drug Misuse and Abuse

The Council VOTED to nominate Dr. Neil Gray, Delegate and Dr. Steven O'Brien, Alternate Delegate, as the two CSMS representatives to the Governor's Task Force On the Prevention of Prescription Drug Misuse and Abuse.

Assembly of Young Physicians

A communication has been received from the AMA that they are establishing an Assembly of Young Physicians to be comprised of one delegate and one alternate delegate from each state. The Assembly will be granted one delegate with voting privileges in the AMA House of Delegates.

The AMA strongly encourages each state to establish a state-level Assembly of Young Physicians as a means of strengthening the direct and meaningful participation of young physicians throughout the Federation.

The AMA will take the lead through its appointment process and, while doing so, strongly encourages state, county and medical specialty societies to actively seek out and appoint qualified young physicians to appropriate council and committee leadership positions.

CSMS has been informed that the AMA will pay only for the delegate's expenses to attend the meeting of the organization.

Following extensive discussion, the Council approved the concept of establishing a Young Physicians Forum, and VOTED to refer the proposal to the Membership Committee for implementation.

CSMS Committee on Public Affairs

The Committee on Public Affairs recommended to the Council that it authorize it to begin publishing in 1987 a CSMS Annual Membership Directory which would

a) list members alphabetically, geographically and by specialty.

b) contain organizational listings of state, county and specialty societies.

c) list appropriate local, state and national associations and organizations of medical interest.

d) contain additional data and information traditionally carried in other county and state medical directories.

The Committee reports that it is reasonable to expect that the project will be self-supporting through appropriate advertising.

The Council VOTED to authorize publication of a CSMS Annual Membership Directory, beginning in 1987.

Communication From New Haven County Medical Associaton

A. Consideration of a proposal from Dr. George Bonner to extend dues to the age of 70 for members in active full time practice was deferred until a report on the subject is available from the Subcommittee on Bylaws in October.

B. No action was taken on a proposal to establish an annual Cost of Living Adjustment (COLA) for the Courtesy Card program.

CSMS History—FOR Information

The Council VOTED to write a letter to Dr. Frederick Weber thanking him for his years of dedicated service to organized medicine and for the historic new articles on CSMS. The Council also VOTED to approve exhibition of the historical materials at the House of Delegates meeting.

Life Members

Following is a list of Life Members, effective 1/1/86 approved since last Council meeting:

Francis J. Albis, M.D., 60 Edward St., East Haven (NH)
Elliott S. Brand, M.D., 123 York St., New Haven (NH)
Joseph M. Danyliw, M.D., 110 Main St., E. Hartford (H)
Jamil Karsh, M.D., 134 Grandview Ave., Waterbury (NH)
Alfred J. Kummer, M.D., 251 Edwards St., New Haven (NH)

Miscellaneous

Dr. Kamens explained that the formula for prospective reimbursements had now been published, and that hospitals stood to gain an average increase in funds of 25%. He pointed out that hospitals were not required to realize that full gain, and in fact one administrator had expressed his inability to get an increase of that magnitude through his Board of Directors. He mentioned that the Commission on Hospitals and Health Care was flooded with inquiries concerning the rate of increase.

Dr. Whalen proposed that the Past President's pin be revised. The Council VOTED to establish a committee, with Dr. Whalen as its chairman, to consider such a revision.

Dr. Whalen also proposed, and the Council VOTED to approve, referral of the Speaker's Bureau program to the Public Affairs Committee which would be responsible for perpetuating the project.

The Council was reminded that the Semi-Annual Meeting was scheduled for November 19, 1986 and it was VOTED that the meeting would start at 12:30 P.M. with a light lunch to be served at noon.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on August 28, 1986. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

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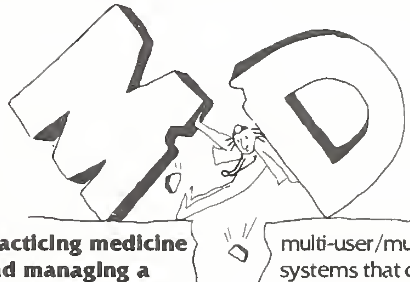

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IN MEMORIAM

BOELHOUWER, CORNELIS, University of Leyden, The Netherlands, 1955. Dr. Boelhouwer was a psychiatrist in the Hartford County area since 1958. He was a key architect in the development of joint psychiatric services between the Institute of Living and Hartford Hospital. First in Hartford County, then in the state and nationally, he was a leader in setting up treatment programs to assist physicians and other health professionals addicted to drugs and alcohol. He was chairman of the State Medical Society's Committee on Mental Health. Dr. Boelhouwer was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died August 31, 1986 at the age of 57.

DOBBS, WILLIAM G. H., University of Rochester, 1934. Dr. Dobbs was a radiologist in the Litchfield County area since 1936. Before retiring to Scottsdale, Arizona, he was on the staff of many area hospitals. Dr. Dobbs was a member of the Litchfield County Medical Association and the Connecticut State Medical Society; died February 14, 1986 at the age of 78.

HODGKINS, CHARLES H., JR., Hahnemann University School of Medicine, 1936. Dr. Hodgkins was a general practitioner in the New Haven area since 1938. He served on the staff of Yale New Haven Hospital and the Hospital of St. Raphael. Dr. Hodgkins was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died June 7, 1986 at the age of 76.

HOWORTH, BECKETT M., Washington University, 1925. Dr. Howorth was an orthopedic surgeon in the Fairfield County area since 1948. From 1951 to 1976, he served as chief of orthopedics at Greenwich Hospital. Dr. Howorth was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died July 16, 1986 at the age of 83.

KANGOS, JAMES A., Tufts University School of Medicine, 1977. Dr. Kangos was a general practitioner in the Windham County area since 1981. He was a member of the medical staff of Hartford Hospital and Windham Community Memorial Hospital. Dr. Kangos was a member of the Windham County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 4, 1986 at the age 34.

KEYS, ROBERT D., University of Kansas, 1927. Dr. Keys was an orthopedic surgeon in the Fairfield County area since 1938. In addition to his affiliation with Norwalk Hospital, he was a member of the medical staffs of Stamford Hospital and St. Joseph's Hospital in Stamford. Dr. Keys was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 13, 1986 at the age of 89.

MATTIE, LOUIS R., Yale University, 1952. Dr. Mattie was an internist in the New Haven County area since 1953. Besides his private practice, he was an assistant clinical professor of medicine at Yale University School of Medicine and associated with Yale-New Haven and St. Raphael's hospitals. Dr. Mattie was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died June 22, 1986 at the age of 65.

MURPHY, JOHN D., University of Maryland School of Medicine, 1954. Dr. Murphy was an anesthesiologist in the Hartford County area since 1957. He served in the anesthesiology department of St. Francis Hospital and, in 1976, joined the Woodland Anesthesiology Associates. Dr. Murphy was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 4, 1986 at the age of 57.

SOREFF, LOUIS, Tufts University School of Medicine, 1932. Dr. Soreff was a general practitioner in the Middlesex County area since 1933. Besides being in private practice, he was on the staff of Middlesex Memorial Hospital. Dr. Soreff was a member of the Middlesex County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 17, 1986 at the age of 78.

STEINBERG, MICHAEL G., New York University, 1968. Dr. Steinberg was an internist in the Fairfield County area since 1975. He was on the staff of both Stamford and St. Joseph's Hospitals. Dr. Steinberg was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died July 24, 1986 at the age of 42.

TOLL, NINA, Yale University, 1941. Dr. Toll was a psychiatrist in the Middlesex County area since 1947. At the time of her death she was in private psychiatric practice in Middletown. Dr. Toll was a member of the Middlesex County Medical Association, the Connecticut State Medical Society and the American Medical Association; died May 22, 1986 at the age of 88.

WILSON, JAMES M., University of Glasgow, 1959. Dr. Wilson was an internist in the Hartford County area since 1962. He was a director of New Britain General Hospital and also was involved with the Visiting Nurses Association and helped the organization establish a hospice program for cancer patients. Dr. Wilson was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died July 8, 1986 at the age of 56.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Full-time position for American trained physician in community hospital in NW Connecticut. Send CV to Lawrence Ward, M.D., Winsted Memorial Hospital, Winsted, CT 06098.

Excellent full time position available at St. Mary's Hospital in Connecticut for a talented physician with experience in Emergency Medicine. There is excellent medical staff support in all specialties and we have an outstanding hospital-based EMS System with paramedic staffing. Our location in Waterbury combines the utmost in family living with proximity to the cultural advantages of Hartford and New Haven. Excellent compensation and benefits accompany this opening. Please send CV to Louis Gottlieb, M.D., Director, Emergency Medical Services, St. Mary's Hospital, 56 Franklin Street, Waterbury, CT 06702, or call (203) 574-6010.

EMERGENCY MEDICINE/INTERNAL MEDICINE

Urgent Care Physician. Emergency Medicine or Internal Medicine physician needed for free-standing walk-in treatment center in central Connecticut. Board certified preferred. Benefits and competitive salary. Send CV to: A.M.G., P.O. Box 937, Avon, CT 06001.

Physicians. Licensed in Connecticut. For house calls on a fee for service basis; West Haven, Milford, Orange area. Malpractice insurance provided. *Pre-screened patients.* Apply with CV and copy of license to CSMS, c/o EM/BY.

FAMILY PRACTICE

Part time family practitioner needed for physician's office. Please call 248-8142.

For Sale. Family practice, no Pediatrics. Excellent location in southern Fairfield County, CT. Good opportunity for Spanish speaking physician. Please send replies to CSMS, c/o FP/QQ.

INSTITUTIONAL/INDUSTRIAL MEDICINE

JCAH accredited, Medicare/Medicaid certified, 103-bed hospital specializing in alcohol and substance abuse, seeking physician to provide diagnosis, care and treatment of patients in small, urban State hospital. Completion of an approved residency training program and a license to practice medicine and surgery in Connecticut is required. No routine "on call" duty. Salary commensurate with experience and training plus full State benefit package and bonus for board certification. Please contact Dr. Marilynn Stuart at 566-3058.

Expanding multi-specialty clinic in central Connecticut looking for BC/BE internist, pediatrician, obstetrician/gynecologist and physician to direct and practice in a walk-in center. Excellent salary and fringe benefits. Send CV to CSMS, c/o INST/DW.

INTERNAL MEDICINE

The Northeast Permanente Medical Group, P.C., the Medical Group for the Hartford, Connecticut area of the Kaiser Permanente Medical Care Program's Northeast Region, is seeking BC/BE general internists for 1986 and 1987. The Hartford area serves over 25,000 members from ambulatory care facilities in East Hartford, Farmington, and Windsor. The Medical Group is a multi-specialty prepaid practice organized as a professional corporation. Applicants should have a strong interest in primary care. Salary and benefits are highly competitive. All inquiries and resumes should be addressed to: Physician Placement Dept., Northeast Permanente Medical Group, P.C., 60 Washington St., Suite 401, Hartford, CT 06106.

Internist, BC/BE, with pulmonary subspecialty, for busy internal medicine group in Connecticut. Send CV to CSMS, c/o IM/JE.

General internal medicine specialist wanted for 1987 to join four established solo practitioners in a rural setting who are merging and forming an internal medicine group practice. If interested, please send particulars and CV to CSMS, c/o IM/CX.

B/C or B/E internist sought by three physician primary care group in New Haven, Connecticut. Office well-equipped with laboratory and x-ray facilities. Initial salary with goal toward partnership. Send resume to CSMS, c/o IM/FF.

INTERNAL MEDICINE/FAMILY PRACTICE

Connecticut—Internal Medicine/Family Practice trained physicians BE/BC to join our nationally recognized physician group practicing aggressive clinical medicine in six physician-owned ambulatory primary care centers surrounding Hartford and Norwalk, CT. IM/FP residents rotating through our centers provide teaching opportunities. Send CV to Gregg Grinspan, M.D., Immediate Medical Care Centers, 850 Silas Deane Highway, Wethersfield, CT 06109, or call (203) 721-7393.

OBSTETRICS/GYNECOLOGY

Southwest Connecticut. BC/BE Obstetrician/Gynecologist. Excellent opportunity in well-established progressive practice. Ultrasound; colposcopy; fetal monitoring. Office across the street from hospital. Need fourth partner. Send CV to CSMS, c/o OB/AZ.

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Central Connecticut. Full service community hospital wishes to attract solo practitioner, BC/BE, for private practice. Growing population base; central location. Excellent opportunity for affiliation with a progressive Medical and Administrative staff. Incentive program available to qualified applicant. Send CV to CSMS, c/o OTO/JK.

PART TIME

U.S. Department of Defense needs physicians to do pre-enlistment physicals. Suitable for semi-retired/retired physician and could amount to two or three mornings a week from 8:00 a.m. to 11:00 a.m. Contact Major Mark R. Lehrman, (203) 773-2359.

PEDIATRICS

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Radiation Therapy of Cancer of the Cervix: Experience at a Community Hospital

THOMAS ROBINSON, M.D. AND DAVID ROBINSON, B.A.

ABSTRACT – **The treatment of cancer of the cervix by radiation therapy in a community hospital is presented. Five year survival of patients with disease limited to the cervix is 92.4%. Five year survival of patients with disease into the parametrium or vagina is 53.9%. The figures compare favorably with published results.**

In 1919, Henry Janeway[1] reported the salvage rate of 5027 patients with unstaged cancer of the cervix treated surgically at Memorial Hospital in New York. The 12% salvage rate, and his enthusiasm for intracavitary radium, prefaced technical improvements in the radiation treatment of cervical cancer over the next four decades.

New Britain General Hospital Therapeutic Radiology Department has treated 116 patients between 1972 and 1985 with cancer of the cervix. These women were treated in conjunction with the Gynecologic Oncologists at the University of Connecticut Health Center. The survival, treatment morbidity, and areas of first relapse of these patients is the basis of this report.

This series of 116 patients was treated by external radiation, delivered after 1978 by a Clinac-4 linear accelerator and prior to that date by a cobalt-60 unit, along with intracavitary radium. The Fletcher-Suit tandem and ovoid afterloading system, a refinement of the Curie Institute technique, was utilized for all radium applications. The time-dose schedules of M.D. Anderson Hospital[2] were used, with individualization based on anatomical variations. A minimum of 8000 rad was delivered to the cervix (Point A), and a minimum of 5500 rad was received at the pelvic side walls. An effort was made to keep the rectal dose under 5000 rad and the urinary bladder dose under 5500 rad. Until 1983, doses to specific anatomic points were calculated manually using a point-source technique. Since 1983, a treatment planning computer has been used for these calculations.

Staging was accomplished by examination under anesthesia, proctoscopy, cystoscopy, and x-rays of the large bowel and urinary tract with contrast material. Chest x-rays and complete blood counts were done on all patients. Diagnostic celiotomy was performed on two women. Biopsy of the cervical lesion was done on all patients. Pelvic and abdominal CT scans have been used more frequently over the past five years. The histology on all of the patients was invasive squamous cell.

The patients with cervical cancer treated by radiation at New Britain General Hospital have been placed into three groups for purposes of reporting survival rates. The 53 women in whom the cancer was confined to the cervix, F.I.G.O. Stages IB and IIA, had five year survival of 92.4%. There are two patients with recurrent disease who are living. Both recurred locally four years after treatment.

The 48 patients in whom the disease extended into the parametrium but was not fixed to the pelvic side walls, F.I.G.O. Stages IIB and IIIA, had five year survival of 53.9%. Three patients were Stage IIIA because of lower vaginal extension. No patient with recurrent disease has survived in this group.

The 15 patients with disease to the pelvic side walls, into the bladder or rectum, or with distant metastases who were treated palliatively all died within 18 months of treatment. Five lived past one year.

The survival rates for each group compare favorably with recently reported results from the University of North Carolina,[3] Yale,[4] M.D. Anderson,[2] and the University of Florida.[5,6]

In the group with disease limited to the cervix, there have been six recurrences. Four of these relapses occurred within two years, and all four of these patients have died. In three, the recurrence was local. Two relapses occurred after two years. Both patients are living with local recurrences.

Stage IIB and IIIA patients had 23 recurrences after treatment. All of these patients have died. Fifteen relapses occurred within two years. In nine patients, there was no locally disease-free period. Two had local recurrence, and four had distant metastases as the first evidence of recurring disease. Eight patients of this group had recurrences after two years: four locally and four distant.

Complications from the radiation treatment of cervical cancer in this series of patients were few. Three patients with rectal bleeding were found to have proctitis which

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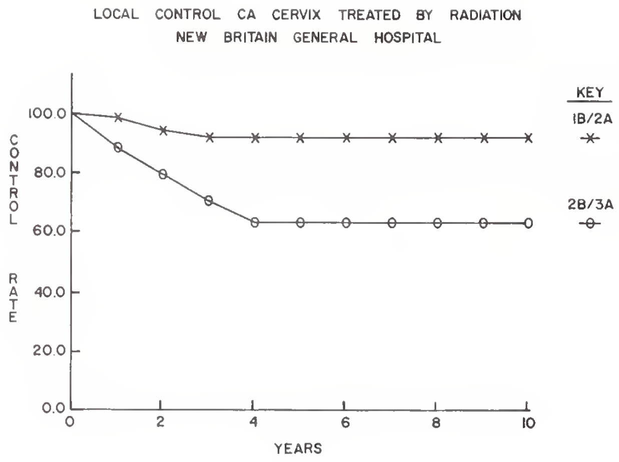

responded to conservative measures. Enteritis successfully treated by resection of a short segment of the small bowel occurred in one patient. Nine years after treatment, a patient who had pelvic inflammatory disease prior to cervical cancer developed a thrombus in a pelvic vein. The etiologic role of the radiation is debatable. One patient with no evidence of pelvic disease ten years after treatment was found to have cancer of the base of the tongue, obviously unrelated to her cervical cancer or the radiation.

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The Use of Electricity in Treating Ununited Fractures

MICHAEL J. BROOM, M.D. AND HARRY R. GOSSLING, M.D.

The failure of fractures to unite is one of the more challenging problems confronting the orthopaedic surgeon. In spite of advances in fracture care and fixation, nonunions continue to pose a difficult and not infrequent problem. The management of nonunions often entails multiple operations and a considerable length of time. An ununited fracture can thus be a tragedy to the patient and a significant economic drain. The treatment of nonunions has traditionally required bone graft surgery, often combined with various forms of internal fixation. More recently, electricity has been used to restimulate the healing process.

Fracture Healing

In order to understand how electricity may affect healing, it is important to review the biology of normal fracture repair. The healing of non-rigidly fixed fractures has traditionally been described in four histologic stages:[24]

1. Inflammation, hematoma
2. Soft callus or cartilage
3. Hard callus
4. Remodelling

The phase of inflammation begins at the time of injury when a hematoma forms between the fracture ends. There is local vasodilatation and polymorphonucleocytes, macrophages and mast cells are brought to the area. Fibrocartilage then appears and eventually connects the bony fragments. A healing fracture is often called "sticky" at this stage. Next, the fibrocartilage calcifies and, by the process of endochondral ossification, fiber bone is formed.[6] This process has been shown to be histologically and biochemically similar to the ossification occurring at the epiphyseal growth plate.[22] Finally, in the stage of remodelling, the fiber bone gradually converts to lamellar bone and the medullary canal reconstitutes.

The factors responsible for initiating or "turning on" the osteogenic process in fracture healing are not known. We do not know what causes cartilage cells to form in the

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MICHAEL J. BROOM, M.D., Orthopaedic Resident; HARRY R. GOSSLING, M.D., Professor and Chairman; both of the Department of Orthopaedic Surgery, University of Connecticut Health Center, Farmington, CT.

fracture gap and then ultimately ossify. Nor do we know what causes osteocytes, periosteal cells and endosteal cells to form bone after a fracture. Possible factors which may induce osteogenesis at the fracture site include: (1) oxygen gradient; (2) bone morphogenic protein (BMP) and (3) electrical potentials.[6]

Brighton has shown that a healing fracture callus has a low tissue oxygen tension.[13] A similar state of relative hypoxia exists in the calcifying portion of the growth plate, and it has been hypothesized that low tissue oxygen tension favors bone formation.[12]

BMP is a partially defined glycoprotein reported by Urist to be capable of stimulating bone formation.[29] Its role as an inductor of osteogenesis in the fracture callus remains to be demonstrated.

Change in electrical potentials after fracture is another factor which may initiate fracture healing. It has been shown that active areas of bone growth, such as the growth plate and a healing fracture callus, are electronegative, while areas less active are relatively electropositive.[17,19]

Fracture Nonunion

Fortunately, most fractures heal uneventfully if managed properly. Some fractures, however, take a long time to heal or fail to do so. Delayed union is said to exist if the healing rate is significantly slower than for the average fracture of similar type and location. Nonunion is present when all reparative processes have ceased and bony continuity has not been restored. It has been estimated that there are approximately 2 million cases of long-bone fractures each year with 100,000 new cases of nonunion, or a 5% incidence of nonunion in long bone fractures.[21] Certain fractures have a higher incidence of nonunion. These include subcapital hip fractures, basilar odontoid fractures (Type 2), and scaphoid fractures.

Unfortunately, no completely suitable animal model for nonunion has been available and, thus, the biologic basis of nonunion in humans is not known. A number of conditions, however, are known to contribute to nonunion. Inadequate immobilization is a well known factor contributing to nonunion. Excessive motion at the fracture site may cause disruption of newly forming vascular channels and result in relatively avascular tissue in the fracture gap which does not have the potential to heal. Those nonunions with excessive mobility for a long time may go on to form a synovial pseudarthrosis. The bone ends become sclerotic and smooth and a fluid-filled synovial-like membrane forms. The humerus has the highest incidence of synovial pseudarthrosis (57.1%).[16] The presence of a synovial pseudarthrosis can be detected by technicium bone scan, which shows a lucent cleft instead of diffuse increased uptake as seen in most nonunions.[16]

Inadequate fracture reduction is another condition which may result in delayed union or nonunion. A longer time is needed to re-establish blood supply across the fracture if there is poor apposition of bone ends or if there is over-distraction. Urist has shown that union is delayed by 12 to 18 months by a gap of one-half centimeter.[31]

Fractures tend to take longer to heal and are at greater risk of developing nonunion if there is extensive soft tissue damage around the fracture site. This is in large part due to disruption of local blood supply. Perhaps equally important is the fact that surrounding muscle provides electrical potentials that may stimulate healing.[21] Devitalization of surrounding muscle eliminates this potential.

Surgery may contribute to the development of nonunion. Periosteal stripping and surgical injury to surrounding soft tissue can delay healing. In addition, inadequate internal fixation which distracts fracture fragments or allows excessive motion may lead to nonunion. Other conditions which may contribute to nonunion include infection, bone loss, and malignant tissue at the fracture site. A significant number of nonunions, however, have no known cause.

Histologically, nonunions may show all elements of normal fracture healing, namely fibrous tissue, fibrocartilage and new bone. There tends to be more fibrous tissue and cartilage and less new bone than in a normal healing callus.[6] Urist's study of human long bone nonunions showed that fibrous tissue persists in the fracture gap but may transform to fibrocartilage.[30] The presence of fibrous tissue and/or fibrocartilage in the fracture gap may persist indefinitely. The treatment of nonunions is aimed at restarting the ossification process which has been arrested. Traditionally, bone graft surgery and more recently electrical sitmulation have been used to restart the healing process.

Electricity and Fracture Healing

The electrical properties of bone have been thoroughly investigated and well described. There are two types of electrical potentials arising in bone.[6] The first is a stress generated or strain related potential, which arises when bone is mechanically stressed. It has been shown that bone under compression is electronegative and bone under tension is electropositive. These potentials arise from the molecular structure of bone and are not dependent on cell viability. They are thought to be due to piezoelectricity and/or streaming potentials. The second type of potential is a bioelectric potential or steady state potential. This potential is dependent on living cells and is independent of stress. Areas of active growth and repair, such as the growth plate and a healing fracture callus, are electronegative. Areas less active are relatively electropositive.[17,19]

These findings have led to attempts to stimulate bone formation using electricity. It has been shown experimentally and clinically that an osteoblastic response is stimulated when electricity of proper current and voltage is applied to bone, either with direct current (cathode/anode system), capacitive coupling, or inductive coupling via pulsating electromagnetic fields (PEMF).[3,4,14,16,20,23,32] A number of studies have demonstrated the efficacy of electricity in treating human nonunions.[2,10,13,14,19]

The mechanism of electrically induced osteogenesis is unknown. A great number of experiments have been undertaken to help elucidate the process, and several theories have evolved. For instance, in systems employing a cathode inserted directly into the fracture gap, profound changes in the microenvironment occur. Specifically, the cathode consumes oxygen and produces hydroxyl ions.[9] This tends to raise pH and lower tissue oxygen tension. There is considerable evidence that both of these conditions favor bone formation.[8]

Electricity may also have a direct effect on the cell, especially at the level of the cell membrane. This may be the major effect produced by pulsating electromagnetic fields. Pilla proposed that PEMF has an effect on cell membrane processes causing an alteration in genetic activity.[28] Norton's work has shown that electrical perturbation may exert its effect through activation of cAMP.[26]

In order for PEMF to be effective, there must be tissue in the fracture gap capable of responding to electrical perturbation. According to one theory,[25] PEMF generates a current in a susceptible fibrocartilage matrix, activating the enzyme lysozyme. The lyosozyme, in turn, catalyzes the disaggregation of glycosaminoglycan (GAG), releasing hyaluronic acid. This results in a local increase in pH, possible activation of alkaline phosphatase, and subsequent tissue calcification and bony healing of the nonunion.

Current Use of Electricity in Treating Nonunions

At present, there are four FDA approved devices available for electrically stimulating osseous healing. The first is a totally implantable direct current stimulator. This was developed by Dwyer and Wickman and was initially used for promoting healing of posterior spinal fusions.[15] This system was further refined by Paterson who reported 86% success in treating 84 patients with delayed unions and nonunions.[27] Lunceford reported 75% success in 102 patients.[10] In this unit, the cathode is inserted through a cortical window adjacent to the nonunion site into the medullary canal and into the fracture gap. The anode and generator are placed beneath the deep fascia. The advantage of this system is that it is completely portable and does not rely on patient compliance. The disadvantage is that it requires two operations, one for implantation and one for removal, with a risk of infection at least as high as bone graft surgery. In addition, the system cannot be used in the presence of infection.

The second system is the semi-invasive direct current unit developed by Brighton and Friedenberg.[11] In this system, four cathodes are inserted percutaneously into the nonunion site. The anode is an adherent pad placed on the skin, and the generator is placed external to the skin under the cast. The system is completely portable, but requires patient compliance. It cannot be used in the presence of infection. Brighton reported a success rate of 73% in 418 patients using this technique.[7]

The third system available is pulsating electromagnetic fields (PEMF). This method was designed by Bassett, Pilla, and Pawluk.[5] PEMF are developed by a pulse generator supplying a time varying current to a pair of coils mounted on the external surface of the cast or extremity.[1] The pulsed electromagnetic fields radiate from the coils through the cast and extremity. An electric field exists at right angles to the electromagnetic field and, through ionic inductive coupling, creates an electric current in the fracture gap tissues. This current triggers calcification and results in bony union.[1]

In a combined international study, Bassett reported the results of PEMF in 1,007 nonunions.[3] The technique had a success rate of approximately 80% in lower extremity nonunions, with slightly less success in upper extremity nonunions. The advantage of this system is that it is completely non-invasive and can be used in the presence of osteomyelitis. The disadvantage is that it is not portable; the coil apparatus must be plugged into a generator unit for ten hours per day. This is the system which is currently employed at the University of Connecticut Health Center Bone Stimulation Clinic, where approximately 100 nonunions have been treated with electricity since 1979.

Most recently, Brighton has reported preliminary results using capacitively coupled electric fields to treat nonunions.[14] In this system, stainless-steel capacitor plates are placed on the skin surface overlying the site of nonunion. A success rate of 77% was achieved in 22 nonunions. This system is also completely non-invasive.

Evaluation of Candidates for Electrical Therapy

Accepted contraindications to the use of electrical therapy include the presence of synovial pseudarthrosis, uncontrollable fracture motion, and a wide fracture gap exceeding one centimeter or half the diameter of the bone.[1] Patient evaluation thus includes a careful clinical examination to assess fracture mobility and a critical review of the radiographs. As already mentioned, technicium bone scan may be helpful in identifying a synovial pseudarthrosis.[16]

Despite efforts to identify appropriate candidates for PEMF, a failure rate of approximately 20% still remains. Some of these failures may be due to poor coil placement and deviation from basic principles of orthopaedic management. Other failures can be attributed to factors in the fracture gap which have not been clearly identified, but which may be responsible for the ineffectiveness of electricity. The more accurate identification of patients who will respond favorably to PEMF will prevent further unnecessary immobilization in the group of patients who will not attain union with coils, and who would more appropriately be treated with surgery.

In an attempt to more accurately predict the response of specific nonunions to PEMF, a study was begun at the University of Connecticut Health Center using biopsy of the fracture gap tissues. Biopsies are obtained in the operating room percutaneously with a trocar needle. The specimens have been examined histologically. More recently, special stains have been employed to analyze the gap tissue. The presence of fibrocartilage in the gap has been correlated with a positive response to PEMF, while the presence of predominantly dense connective tissue has been associated with a failure of PEMF. Further microanatomic and biochemical analyses are planned in the future. We hope the added information will further increase the accuracy of the fracture gap biopsy in predicting the applicability of PEMF to specific nonunions, and perhaps even add to our understanding of the pathobiology of fracture nonunion.

Summary

Although the exact mechanism of electrically induced osteogenesis remains unknown, numerous clinical trials have confirmed the effectiveness of electrical stimulation in treating nonunions. Success rates comparable to bone graft surgery have been achieved, with lower associated risk. Current research aimed at more accurately identifying appropriate candidates for electrical therapy will increase success rates and shorten disability time in this group of patients who have already been significantly disabled.

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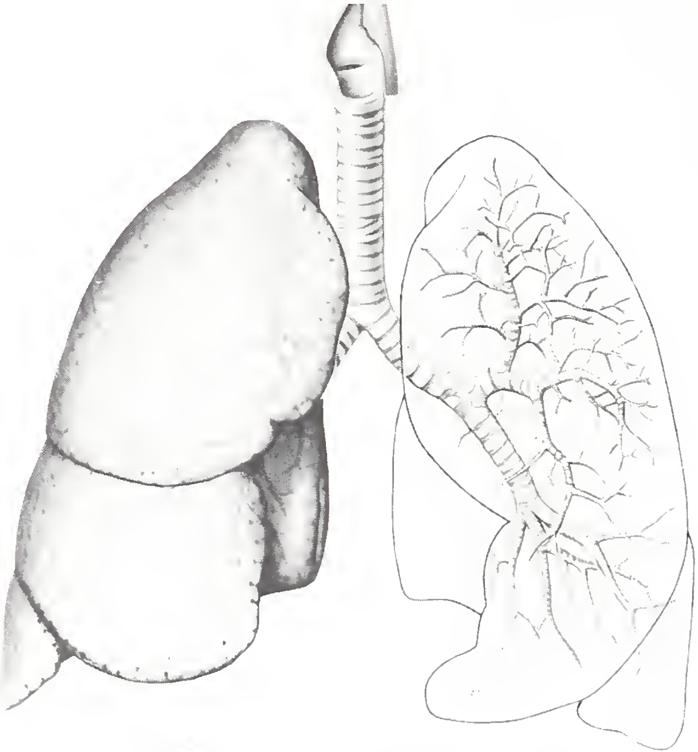

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Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy – Pregnancy Category B – Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor® (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers – Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children – Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions. Adverse effects considered related to therapy with Ceclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain – Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic – Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic – Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal – Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

Note. Ceclor® (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Arthroscopic Synovectomy of the Knee

ROBERT L. FISHER, M.D. AND THOMAS W. DUGDALE, M.D.

ABSTRACT—The results of arthroscopic synovectomy in 18 knees of 16 patients with chronic synovitis of variable etiology were reviewed. About half of the patients were improved, and the remainder were unchanged or developed progressive deterioration from associated articular surface abnormality. The procedure has very little morbidity and should replace open synovectomy for management of those cases of chronic synovitis which are refractory to medical management before instability or articular surface abnormality develop.

Schuller is considered to have performed the first knee synovectomy in 1887.[1] Dr. Paul P. Swett, a Hartford, Connecticut, orthopedic surgeon, carried out the first knee synovectomies for rheumatoid arthritis in this country.[2] Swett's reports in 1923 and 1938 did much to popularize the operation.[3] The procedure fell into disfavor after Ghormley and Cameron's report in 1941 indicated about 50% poor results in rheumatoid arthritis.[4] In recent years, synovectomy has become an accepted method of treated pigmented villonodular synovitis and synovial chondromatosis.[5] The role of synovectomy in rheumatoid arthritis is controversial though most authors feel the operation is indicated in those patients with synovitis refractory to medical treatment in the absence of joint surface destruction, instability, and flexion contracture.[5,7]

Recently, arthroscopic techniques have been developed such that synovectomy may be carried out without the morbidity that usually accompanies the open procedures. While arthroscopic surgeons have been generally enthusiastic about the operation,[8-10] there have been very few reports[11,12] documenting the results of arthroscopic synovectomy in conditions other than hemophilic arthritis.

Materials and Methods

Twenty consecutive arthroscopic synovectomies in 18 patients during 1981-1985 were reviewed. Two patients were lost to follow-up. The remaining 16 patients (18 procedures) were studied by chart and x-ray review and by follow-up questionnaire.

There were 9 female and 7 male patients. All knees had chronic synovitis preoperatively which had been refractory to medical management and responsible for pain, swelling, or other symptoms. The diagnosis was rheumatoid arthritis (8 knees), juvenile rheumatoid arthritis (2 knees), chronic synovitis of unknown etiology (3 knees), synovial chondromatosis (2 knees), Lyme arthritis (1 knee), pigmented villonodular synovitis (1 knee) and probable degenerative arthritis (1 knee). The average follow-up time was 27.2 months (range 11-54 months).

All operations were performed as outpatient surgeries using tourniquet and general anesthesia. Four puncture wounds were generally employed: superior-medial, superior-lateral, inferior-medial, and inferior-lateral. Standard Storz 30° and 70° arthroscopes, and inflow canula and synovial resectors were positioned through the portals in order to visualize and systematically remove the synovium as completely as possible. In the later cases, posterior-medial and posterior-lateral portals were also added to achieve removal of the synovium of the posterior compartments of the knee. A fairly complete resection of synovium from the suprapatellar pouch, medial and lateral recesses, intercondylar notch, and perimeniscal areas was accomplished in all knees. The procedures required 90-120 minutes to complete.

Postoperatively, the patients were permitted immediate weightbearing and started on isometric quadriceps strengthening exercises. A compressive dressing applied in the operating room was removed on the fifth postoperative day, and the patients returned for office visits at about two weeks postoperatively.

Results

The results are summarized in Table 1. Subjectively the patients felt that 9 knees were better, 2 worse, and 4 the same as preoperatively. Seven knees had no swelling, 3 were less swollen than before operation, and 5 were unchanged. Twelve knees swelled less often, 2 more often, and 1 as often after surgery. Eight patients were more active, 3 less active, and 4 unchanged after synovectomy. Three knees required total knee replacement after arthroscopic synovectomy. One patient with undiagnosed chronic synovitis and significant joint surface abnormalities

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Table 1
RESULTS OF ARTHROSCOPIC SYNOVECTOMY

						Patient Assessment—Post Op. Compared to Pre Op.			
Case	*Sex*	*Age*	*Diagnosis*	*Operative Findings at Arthroscopy*	*F/U*	*How the Knee Feels*	*Knee Swelling (Degree)*	*Knee Swelling (Frequency)*	*Activity*
1.	F	35	RA	Chondrom. Patallea	54 mos.	Same	Same	Less Often	More
2.**	F	49	RA	DJD MFC	43 mos.	(S/P TKR)			
3.**	F	49	RA	DJD MFC	41 mos.	(S/P TKR)			
4.**	F	30	RA	Mild DJD, Loose Bodies	34 mos.	Better	None	Never	More
5.**	M	50	RA	Smooth Joint Surfaces	27 mos.	Better	None	Less Often	Less
6.	F	30	RA	Mild DJD, Loose Bodies	21 mos.	Better	None	Never	More
7.	F	49	RA	ACL/PCL Laxity	15 mos.	Worse	Same	More Often	Less
8.	M	16	Lyme Arthritis	Pannus Over Anterior Femur	46 mos.	Better	None	Never	More
9.	M	46	Chronic Synovitis	Smooth Joint Surfaces	39 mos.	Better	None	Never	More
10.	M	58	Chronic Synovitis	DJD and Pannus MFC	24 mos.	(S/P TKR)			
11.	F	34	Chronic Synovitis	Smooth Joint Surfaces	11 mos.	Better	None	Never	More
12.	F	35	Synovial Chondrom.	Chondrom. Patellae DJD LFC	34 mos.	Same	Less	Less Often	Less
13.	F	60	Synovial Chondrom.	DJD Both FC's	17 mos.	Better	Less	Less Often	Same
14.	M	10	JRA	Smooth Joint Surfaces	27 mos.	Same	Same	Less Often	Same
15.	F	10	JRA	Smooth Joint Surfaces	16 mos.	Better	None	Less Often	More
16.	F	18	JRA	Irregular MFC	14 mos.	Worse	Same	More Often	Same
17.	M	56	Degen. Arthritis	Chondrom. LFC and Lateral Tibia	14 mos.	Same	Same	Same	Same
18.	M	60	PVNS	Bloody Effusion Smooth Jt. Surfaces	13 mos.	Better	Less	Less Often	More

**Bilateral Cases (2,3,4&5)

JRA: Juvenile Rheumatoid Arthritis
RA : Rheumatoid Arthritis
DJD: Degenerative Joint Disease
PVNS: Pigmented Villonodular Synovitis

M/L FC: Medial/Lateral Femoral Condyle
A/P CL: Anterior/Posterior Cruciate Ligament
TKR: Total Knee Replacement
Synovial Chondrom: Synovial Chondromatosis

showed a smooth synovial lining at subsequent open procedure and arthroplasty. Remarkably, he has continued to experience a chronic effusion, even after total knee arthroplasty. One other rheumatoid patient experienced initial improvement in both knees from synovectomy but subsequently had deterioration. In three knees having repeat arthroscopy (2) or open synovectomy (1), the joint lining was remarkably smooth compared to the preoperative villous appearance.

Five knees required aspiration of hemarthrosis at the first office visit after surgery. There were no other complications of the procedure such as infection or neurovascular compromise.

Discussion

The rationale for synovectomy is to remove the primary source of abnormal fluid, the potential pannus for destruction of joint surfaces, and the reservoir for inflammatory enzymes. When the synovitis is secondary to degeneration of the articular surfaces, this procedure cannot theoretically be expected to be effective (cases 10 and 15). Unfortunately, a precise diagnosis cannot always be made preoperatively. In cases of primary localized synovial diseases such as synovial chondromatosis or pigmented villonodular synovitis, resection of the involved synovium should be beneficial. This was true in our study except for one case of synovial chondromatosis in which joint surface abnormalities and inability to completely resect the posterior synovium left the patient essentially unchanged (case 6). In rheumatoid arthritis, a systemic disease, it is not clear what the effect of synovial removal is on the joint.[5] It is certain that synovium regenerates.[13] The regenerated synovium, while frequently improved in gross and even histologic appearance,[14] may still show inflammatory changes,[15,16] and harbor inflammatory enzymes.[14] Whether or not synovectomy confers any prophylactic effect on future joint deterioration in rheumatoid arthritis is controversial. One randomized clinical trial suggests that there is no significant difference between knees having, and not having, synovectomies.[17] Laurin, et al. observed a protective effect from synovectomy in 29 patients.[7]

The results of knee synovectomy in this series are comparable to those of open synovectomy for rheumatoid arthritis.[1] As noted by others,[3,5-7] the results were less favorable in cases having joint surface abnormalities or instability. Compared to open synovectomy, the arthroscopic approach has dinstinct advantages. While open synovectomy requires an average two-week hospitalization, usually a manipulation of the knee under anesthesia to restore motion, and many weeks of rehabilitation, arthroscopic synovectomy can be performed as an outpatient, and the patient may quickly return to regular activities. Moreover, synovectomy can be more completely accomplished arthroscopically than by open methods.[9,11]

On the basis of the limited results of this study, we would recommend arthroscopy and arthroscopic synovectomy for patients having chronic synovitis without significant instability or joint surface abnormalities. The procedure is contraindicated in degenerative arthritis or in cases with abnormal changes of articular erosion or instability.

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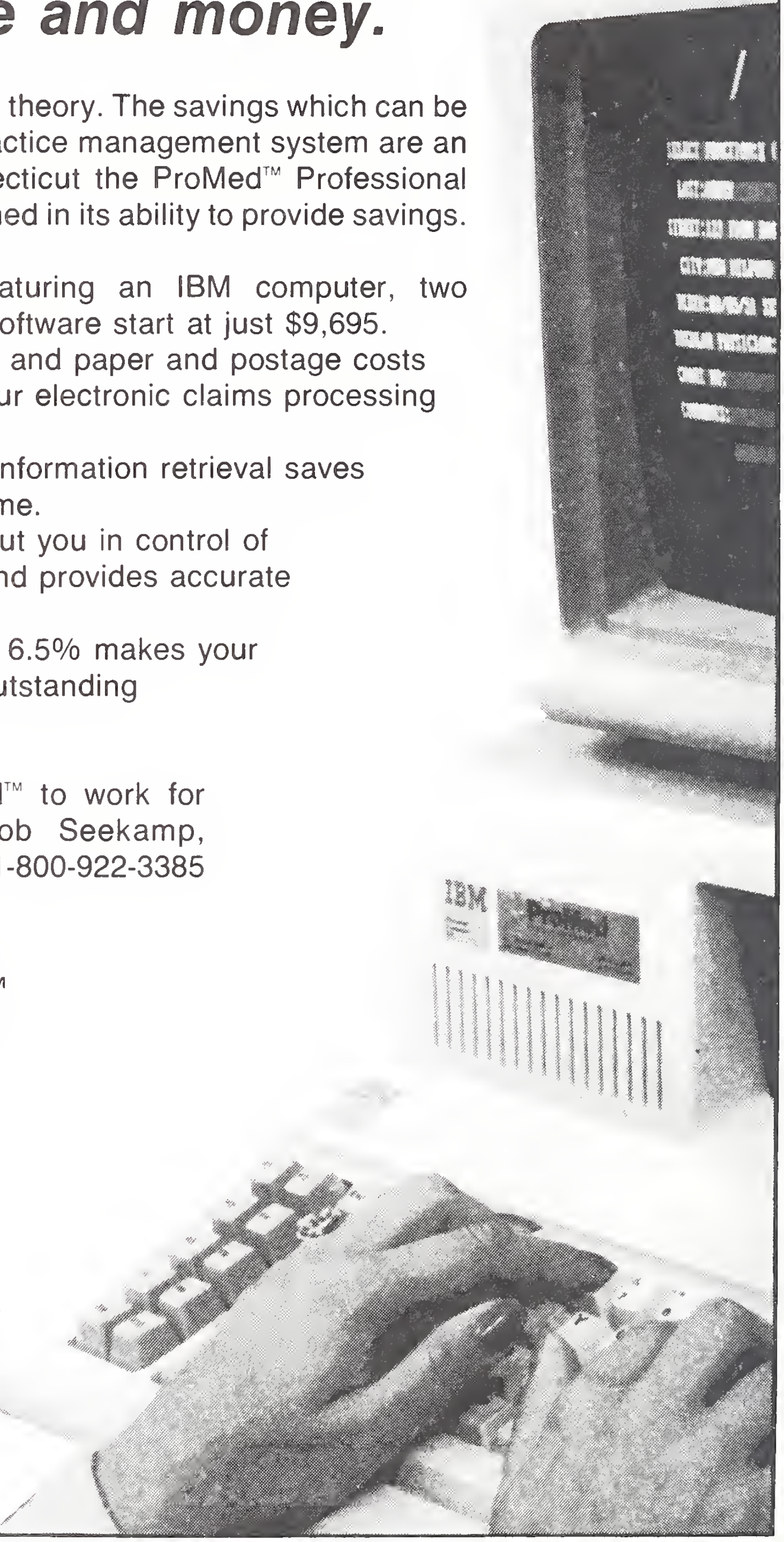

Pheochromocytoma in a Patient with Severe Coronary Artery Disease

LUIS F. DIEZ, M.D. AND HENRY MANNIX, M.D.

ABSTRACT— Pheochromocytoma is a rare but curable cause of hypertension. These tumors vary widely in their vasoactivity and consequently may be difficult to diagnose. When diagnosed and properly treated the results are excellent; left untreated the patient may die of complications of its hypertension. The combination of functional adrenal medullary tumors and coronary artery disease has been reported and several patients have died following coronary artery bypass surgery when the pheochromocytoma was not suspected. Problems in diagnosis and treatment of a patient who underwent coronary bypass surgery prior to excision of a pheochromocytoma are here presented and discussed.

Introduction

Pheochromocytoma is a rare cause of hypertension. Most of the clinical manifestations are produced by the continuous or intermittent release of catecholamines into the circulation. Occasionally the tumors are not functional or may release catecholamines at rates which do not increase plasma levels significantly.

The hypertension produced by a pheochromocytoma is either sustained or intermittent, in which case it presents as paroxysmal episodes. Sudden release of catecholamines can lead to arrhythmias, cerebrovascular accidents and even death. Undiagnosed pheochromocytomas have been implicated in the death of up to 73% of patients with unsuspected tumors.[1]

We report the case of a patient with an adrenal mass, suspected to be a pheochromocytoma, who also had severe coronary artery disease. Although the biochemical evidence suggested that the tumor intermittently secreted catecholamines, a conclusive diagnosis of a pheochromocytoma was difficult to reach. Following recovery from coronary artery bypass, catecholamines levels were again found to be elevated. Subsequent adrenal surgery proved this lesion to be a pheochromocytoma. Electron microscopy studies confirmed the presence of secreting granules.

Report of a Case

A 58 year old obese, diabetic, hypertensive female with history of angina presented with increase frequency and severity of chest pain. Review of systems disclosed recent episodes of sweating, flushing and lightheadedness accompanied by shortness of breath. Medications included insulin, oral and sublingual nitroglycerin, nifedipine, carbamezipine, lorazepam and quinidine sulfate. On admission the blood pressure was 140/84, pulse was 72 per minute and regular. The patient was in no apparent distress. Heart, lung and abdominal examinations were unremarkable. The diagnosis of unstable angina was made. The patient responded to medical treatment. On a subsequent admission to another hospital fluctuations were noted in her blood pressure, with systolic ranging from 104 to 180 and dyastolic from 58 to 100 mm.Hg. In a 24-hour urine collection VMA was 6.4 mg/24° (normal 0.7-6.8 mg/24°) and total free catecholamines were 478 ug/24° (normal 0-103 ug/24°). Ultrasound of the abdomen showed a left suprarenal mass, approximately 2 cm. in size. Overnight dexamethasone suppression test was normal. Serum aldosterone was 2ng/ml in the absence of diuretics. Plasma renin activity was 0.3 ng/ml in the reclining position and 0.8 ng/ml after 3 hours in upright position. Several measurements of serum potassium were all normal.

On return to the hospital cardiac catheterization showed three coronary vessel disease. Computerized tomography of her abdomen confirmed the presence of a left suprarenal mass. Multiple determinations of VMA, metanephrines and catecholamines were within normal limits or marginally elevated (see Table 1). The decision was made not to remove the adrenal mass at that time.

Blood pressure was well controlled on nifedipine and nitrates. The patient underwent coronary bypass to the posterior descending, left anterior descending and diagonal coronary arteries. No episodes of hypertension, hypotension or arrythmias were noted during anesthesia induction or during surgery. Postoperatively the patient had several episodes of vague chest discomfort and night sweats; the course and recovery were otherwise uneventful. On subsequent outpatient visits the patient complained

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Table 1

URINE COLLECTIONS FOR VMA, METANEPHRINES AND CATHECHOLAMINES

	VMA (2-10 mg/24°)*	*Metanephrines* (0.0-1.0 mg/24°)	*Total Catecholamines* (0-100 ug/24°)	*Epinephrine* (<20 ug/24°)	*Norepinephrines* (20-83 ug/24°)
6/10/82	5.2 mg/24°	1.9 mg/24°	169 ug/24°	105 ug/24°	64 ug/24°
6/11/82	5.3 mg/24°	1.4 mg/24°	92 ug/24°	12 ug/24°	80 ug/24°
6/18/82	4.9 mg/24°	1.7 mg/24°	110 ug/24°	(N/A)	(N/A)
6/19/82	6.0 mg/24°	1.4 mg/24°	57 ug/24°	33 ug/24°	24 ug/24°
6/20/82	5.3 mg/24°	2.1 mg/24°	98 ug/24°	(N/A)	(N/A)
6/26/82	+ 3.8 mg/12°	.4 mg/12°	34 ug/12°	6 ug/12°	28 ug/12°
10/25/82	10 mg/24°	1.7 mg/24°	50 ug/24°	(N/A)	(N/A)
11/18/82	10 mg/24°	1.6 mg/24°	101 ug/24°	(N/A)	(N/A)

+ 12 hour urine collection started immediately after episode of chest, pain, flushing, sweating and blood pressure elevation.

(N/A) Fractionalization of total catecholamines not available.

* Normal values given in parenthesis.

of persistent episodes of flushing and sweating. Increases in blood pressure up to 190/90 were also recorded. A decision was taken to remove the adrenal mass. Prior to abdominal exploration repeated catecholamines levels were mildly elevated (see Table 1; values of November 18, 1982).

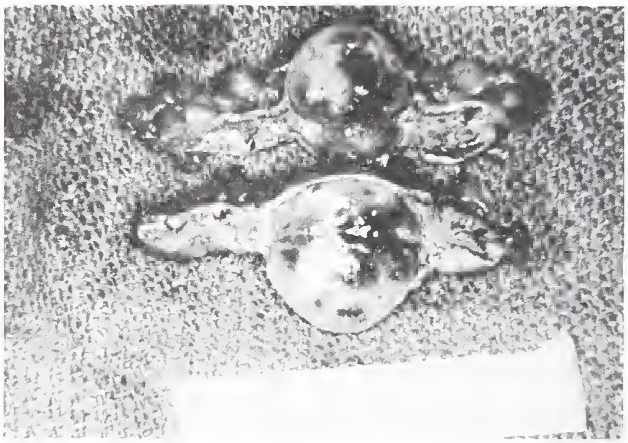
In preparation for surgery the patient was started on phenoxybenzamine. Surgery was delayed due to development of sick sinus syndrome and pneumonia which responded well to antibiotics. After resolution of the pneumonia and the insertion of a permanent pacemaker, a left adrenalectomy was performed through a left subcostal incision. Episodes of hypertension (up to 190/85) were noted at the time of mobilization of the tumor. A 2.2 centimeter in diameter mass occupied the medullary portion of the adrenal gland (Figure 1). Microscopic examination showed small, solid clusters of apposed tumor cells within an elaborate capillary stroma. Individual cells were large, with abundant, granular cytoplasm and variable sized nuclei with condensed chromatin and nucleoli (Figure 2). Electron microscopy demonstrated the presence of abundant neurosecretory granules. Eccentric dense cores of the secretory vesicles were considered to be characteristic of a pheochromocytoma.

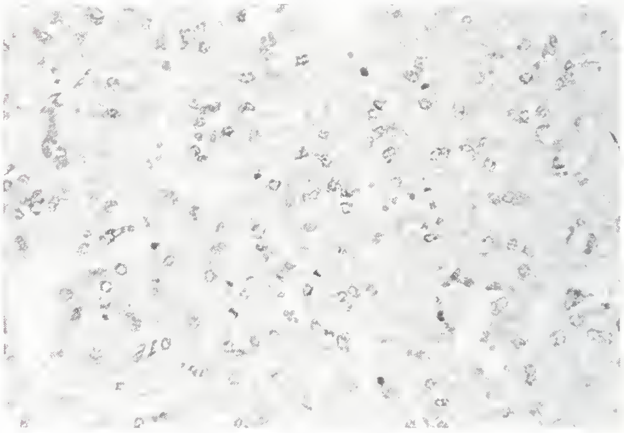
The patient had no complications or hypertension postsurgically. There were no more episodes of flushing and sweating reported on follow-up visits.

Discussion

Patients with pheochromocytoma are at risk of cardiovascular death. Cohen and Dent reported 34 patients with pheochromocytoma of which 10 died of acute cardiovascular death. In 8 of these cases the tumors were not suspected by the attending clinician.[2] Sutton and associates found that the diagnosis of pheochromocytoma was made at the time of autopsy in 41 patients during a period of 50 years. Death was felt to be related directly or indirectly to the unsuspected tumor in 30 of these 41 patients with 11 having intraoperative hypertensive or hypotensive crises.[1] Death during or after surgical procedures as a complication of unsuspected pheochromocytoma have been well documented.[3]

The patient here presented had severe coronary artery disease with frequent episodes of chest pains. It has been suggested that a pheochromocytoma may produce coronary artery spasm and chest pains due to the high catecholamines concentrations.[4]





Our patient was suspected to have a pheochromocytoma but conclusive biochemical evidence was difficult to obtain. She was able to undergo coronary artery bypass surgery without complications.

Phenoxybenzamine, an antagonist of alpha adrenergic receptors, had been traditionally used in pheochromocytoma. It is a noncompetitive inhibitor of norephinephrine action. Addition of a beta blocker may be necessary if the patient develops arrhythmias; this should be preceded by the use of phenoxybenzamine due to the danger of unopposed alpha activity induced by the catecholamines.

It is possible that the calcium channel blocker (nifedipine) which the patient was taking was suppressing catecholamine secretion from the pheochromocytoma.[5]

It is also possible that at the time of bypass surgery the tumor did not produce significant amounts of catecholamines to cause marked changes in blood pressure. Increases in blood pressure were noted during anesthesia induction and during the manipulation of the tumor at the time it was resected. These increases in blood pressure were moderate and may not have been necessarily related to secretion from the mass. Pathology examination corroborated the diagnosis of a pheochromocytoma with the presence of secretory granules. Intermittent secretion of pressor amines is not uncommonly seen. The degree of vasoactivity varies from tumor to tumor and it is the authors' opinion that the tumor in this patient was not only of low activity but in addition was secreting pressor amines intermittently. These factors may have contributed to the difficulty in making a diagnosis of a pheochromocytoma prior to the removal of the mass. The blood pressure response to induction of anesthesia and tumor manipulation is most characteristic of a functional pheochromocytoma.[6]

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IN AN INTERVIEW IN AMERICAN MEDICAL NEWS (AMN), incoming AMA President John J. Coury Jr., MD, spoke on a broad range of topics. Here are some of his comments:

"I have only one main theme that I will be making to physicians," Dr. Coury says, "and that is that we cannot let down on the quality of medical care. That's a physician's major purpose in life—to provide high-quality medicine. We have to strive to keep quality up in the face of the bottom-line pressures being brought against us by business and governments. Right now, the debate between quality care and the bottom-line mentality is pretty intense. The AMA has always been in favor of cost-effective medicine, but there is a limit to how far you can shave costs without endangering quality. Right now, we are pushing those limits to the edge, and the quality physician and the quality hospital will become endangered species unless we can persuade the public to push the pendulum back. The current efforts to limit cost are penny-wise and pound-foolish."

He explains: "Third-party payers are mandating things like having all breast biopsies and all hernias done on an outpatient basis. Well, when you mandate how the physician must practice medicine, you increase the possibility of risk to the patient, including complications, even death. AMA is saying to the third-party payers: 'Enough is enough!' When corporations and governments begin to try to hire physicians and then tell them how to practice medicine, it is time for AMA to resist."

Dr. Coury is optimistic, however. "The emphasis today is on holding down cost," he says, "but the pendulum will swing back. That's because the public will demand it. Back in the 1930s and 1940s, we were told that American medicine would soon be socialized. The same thing happened in the early 1970s. Well, American medicine is still free. It's always been a peak-and-valley type of thing."

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Important Advances in Clinical Medicine

Epitomes of Progress—Pediatrics

The Scientific Board of the California Medical Association presents the following inventory of items of progress in pediatrics. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in pediatrics that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Pediatrics of the California Medical Association and the summaries were prepared under its direction.

Hepatitis B Vaccine

There are several viral agents that may infect the liver in humans and produce hepatitis. These include hepatitis A, or infectious hepatitis, hepatitis B (HBV), referred to in the past as either serum hepatitis or Australian-antigen hepatitis, and a third form produced by the interaction of HBV and another small virus called the δ-particle, which by itself is unable to cause disease. In addition, there are cases of hepatitis that are not A, not B and not δ for which specific laboratory methods of identification are not yet available. There are diagnosed by exclusion and called "non A-non B."

The only vaccine currently available is for HBV; it is a preparation of virus surface particles purified from human plasma and inactivated by a procedure designed to render noninfectious all known types of virus including that which causes the acquired immunodeficiency syndrome, human T-lymphotropic virus type III. Studies with the vaccine have shown that antibody is produced in 80% or more of those who receive the series of three doses and that adequate antibody levels correlate with protection from infection. The vaccine is recommended only for selected segments of the population.

The behavior and frequency of HBV infection varies in different parts of the world and in different subgroups within a country. In China, Southeast Asia and parts of South America and Africa, 5% to 15% of the population acquire the virus at birth or shortly thereafter and have a high risk of chronic hepatitis, cirrhosis or primary hepatocellular carcinoma. Infection in Western Europe and Australia occurs principally among adults and has a much lower prevalence and less of a risk for sequelae. In the United States, the prevalence of HBV infection is about 5% among the general population, but much higher and rapidly increasing among sexually promiscuous young adults who use intravenous drugs or live under crowded, unsanitary conditions. It is estimated that 6% to 10% of these groups become ongoing carriers, that 25% of the carriers progress to have cirrhosis and many die of chronic liver disease or cancer each year.

HBV prophylaxis is available as immediate but temporary passive immunization in the form of a high-titer-antibody immunoglobulin called hepatitis B immunoglobulin or regular pooled immunoglobulin containing a lower titer of antibody to HBV (regular immunoglobulin) and the active long-term protection obtained from hepatitis B vaccine. The immunoglobulin is used for postexposure protection and the vaccine for both preexposure and postexposure prophylaxis. Adverse reactions with the vaccine are few and consist mainly of pain at the site of inoculation. There are insufficient data to predict the total duration of antibody persistence but it appears to be in excess of four years.

Vaccine Administration

Primary immunization includes three doses of vaccine given intramuscularly, with the second and third following the first by an interval of one and six months, respectively. Those at significant risk of HBV infection who should receive the vaccine include:

- Health care workers;

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- Users of illicit injectable drugs;
- Contacts of HBV carriers: household, sex partners, institutional;
- Hemodialysis patients, recipients of possibly HBV-infected products;
- Homosexually active men;
- International travelers, others considered at high risk, and
- Those with accidental percutaneous or sexual exposure (hepatitis B immunoglobulin plus vaccine).

The use of HBV vaccine in newborns delivered of HBV-carrier mothers is discussed in the June 1984 issue of this journal.

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Chlamydia trachomatis in Adolescents

Chlamydia trachomatis is the most common sexually transmitted disease agent, and a young age appears to be an important risk factor related to its genital infections. Prevalence rates for endocervical infection have been reported at between 8% and 22% among adolescent girls attending teen clinics to as high as 37% among those presenting for prenatal care. Although comparable statistics are currently not available, there are indications that chlamydia may be a common infection among adolescent boys as well. Clinical syndromes frequently associated with chlamydial infection include urethritis in males and cervicitis and pelvic inflammatory disease among females.

Infection with *Chlamydia* in patients with pelvic inflammatory disease results in the most serious sequelae—tubal infertility. It has been estimated that a 15-year-old sexually active girl has a risk of 1:8 of pelvic inflammatory disease developing, compared with a risk of only 1:80 in a 25-year-old woman. Yet it is difficult for both patient and physician to recognize chlamydial infections, as patients frequently present with few or no clinical symptoms or signs. A lack of simple, inexpensive and reliable tests has hindered recognition and control of the chlamydial epidemic among adolescents as well. Tissue culture is currently the gold standard of diagnostic tests but requires costly, sophisticated cell culture techniques, does not render an immediate result and is not widely available to most clinicians. Recently less expensive, rapid, nonculture, fluorescent antibody techniques have been introduced. Evaluation of the performance of such tests, however, among populations who do not attend sexually transmitted disease clinics is limited. Among adolescent boys, there is evidence that screening for pyuria in the first-catch urine specimen (10 or more leukocytes per high-power field, spun urine) may be helpful in identifying occult chlamydial urethritis. The rapid nonculture fluorescent antibody techniques appear to be less sensitive in determining chlamydial infection among men (urethra) than among women (endocervix). Such techniques, therefore, are not recommended for screening male patients for chlamydial infection.

In light of our current limited diagnostic capabilities and of the importance of the role of chlamydial infections in infertility, the Centers for Disease Control have made recommendations regarding the screening and treatment of populations considered at high risk for chlamydial infection. All adolescents with the following symptomatic syndromes associated with chlamydia should receive treatment for chlamydial infection: nongonococcal urethritis, mucopurulent cervicitis, pelvic inflammatory disease and epididymitis. Decisions regarding treatment should be made in conjunction with culture results when available. Because mucopurulent cervicitis, pelvic inflammatory disease and epididymitis are also associated with *Neisseria gonorrhoeae* infection, such patients should also receive effective antigonococcal treatment. Sexual contacts of persons with the above clinical syndromes should be evaluated and treated for presumed chlamydial infection. Routine chlamydial screening of asymptomatic adolescent girls, both pregnant and nonpregnant, is recommended using culture (when available) or rapid nonculture fluorescent antibody techniques. Adolescent boys may be screened by culture or by analysis of a first-catch urine specimen, with the knowledge that information on screening asymptomatic young men is limited. While it is anticipated that improved, cost-effective diagnostic capabilities will be available in the future, the importance of *Chlamydia* in the development of infertility among our youth dictates the current recommendations for treatment and screening of sexually active adolescents.

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Intravenous Immune-Globulin Therapy in Pediatric Hematology

Intravenous immune-globulin therapy has recently been shown to be useful in managing autoimmune hematologic disorders. The peripheral blood cells—platelets, erythrocytes and neutrophils—in patients with these disorders are coated with antibodies, predominantly immunoglobulin (Ig)G, and are prematurely removed from the circulation by the reticuloendothelial system, primarily the spleen. The mechanism of action of immune globulin given intravenously (IV) has not been elucidated completely. A number of mechanisms have been proposed, but the best studied and perhaps the most important involves the competitive blockade of specific receptors on macrophages and monocytes within the reticuloendothelial system for the Fc region of the IgG molecule, resulting in improved survival of the antibody-coated cells. Fc-receptor function returns to normal, however, in about four weeks and does not explain the prolonged remission seen in some patients following IV immune-globulin therapy. This suggests that other mechanisms such as decreased antibody production may be involved.

Much of the clinical experience with IV immune-globulin therapy for hematologic disorders has been gained in the treatment of children with immune thrombocytopenic purpura. In several studies a significant rise in the platelet count was shown within one week in 75% to 100% of patients with acute and chronic immune thrombocytopenic purpura. In as many as half of the patients the response is sustained but, in many, periodic booster infusions are required to maintain adequate counts. Children, in contrast to adults, have a higher initial increase in the platelet count, a lower incidence of relapse and a longer duration of response. In addition to this disorder, IV immune-globulin therapy has also been used successfully in the treatment of neonatal isoimmune thrombocytopenia, autoimmune neutropenia and Coombs-positive hemolytic anemia.

The optimal dose of IV immune-globulin has not been established. In most studies 0.4 grams per kg per day was infused over four to eight hours for five consecutive days. A dose of 1 gram per kg per day for one to three days has also been effective. Subsequent booster doses are given as needed. Toxicity has been limited, provided it is given slowly over a number of hours. Headaches have been reported in 20% of patients and occasionally pallor, nausea, fever or chills. The cost of IV immune-globulin therapy is considerable, however, about $70 per gram.

Intravenously given immune globulin clearly is effective in managing immune hematologic disorders, but its precise role in pediatric hematology has not been completely established. Acute immune thrombocytopenic purpura in children is usally a benign, self-limited condition and, under most circumstances, the cost of giving IV immune globulin does not justify its regular use. A more appropriate use of this therapy may be in patients with potentially serious bleeding or as an alternative to splenectomy for some patients.

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Hemophilus influenzae Type b Immunization

A polysaccharide vaccine is now available for the prevention of invasive *Hemophilus influenzae* type b (Hib) disease. Vaccine efficacy is estimated at about 90% for children aged 2 to 5 years. The Hib vaccine induces an antibody response that is directly related to the age of the child. Infants respond less frequently and the current vaccine is of no value in children younger than 18 months.

The Advisory Committee on Immunization Pratices (ACIP) of the Centers for Disease Control and the American Academy of Pediatrics recommend that all children at 24 months of age receive the HIB vaccine. Additionally, children between the ages of 24 and 71 months should be considered for immunization because the vaccine has proved to be safe and effective. Because children aged 2 to 3 years who attend day-care facilities are at higher risk than older children, higher priority should be given to the younger children. The vaccine is not recommended for children older than 71 months or for adults.

Immunizing children aged 18 to 23 months remains controversial. The ACIP recommends that immunization should be considered for children at 18 months of age who are in known high-risk groups, including those attending day-care facilities and children with chronic conditions known to cause an increased risk for Hib disease such as anatomic or functional asplenia (sickle cell disease or splenectomy) and malignant lesions associated with immunosuppression. Children receiving the Hib vaccine at between 18 and 23 months of age may need to be reimmunized 6 to 18 months following the original immunization to ensure protection. Hib and the diphtheria-tetanus-pertussis (DTP) vaccine can be administered simultaneously at separate sites without impairing the immune response to the individual antigens.

Hib immunization is given as a single subcutaneous dose of 0.5 ml. Mild local reactions and low-grade fever may occur, but severe systemic reactions are extremely rare. Simultaneous administration of Hib with DTP does not result in increased reactions to either vaccine. New Hib vaccines are being developed that may provide protection of children younger than 18 months.

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AIDS in Children

Pediatric acquired immunodeficiency syndrome (AIDS) is a distinct immunodeficiency disorder diagnosed on the basis of epidemiologic, immunologic and virologic data. Currently there are about 200 cases of pediatric AIDS that conform to strict diagnostic criteria established by the Centers for Disease Control. There are probably two to three times that number who have AIDS-related disorders. The total number of AIDS cases in children continues to increase at the same rate as in the adult population.

Epidemiologic factors are the initial indicator for the diagnosis of pediatric AIDS. The following are important risk factors: mothers who use drugs intravenously or who are prostitutes, heterosexual mothers with bisexual husbands, a history of blood transfusions within the preceding five years (this interval may require modification as additional information is obtained), infusion with factor VIII concentrate or an infant born into a family where the father has hemophilia. Persons capable of transmitting the AIDS virus (human T-lymphotropic virus type III/lymphadenopathy-associated virus [HTLV-III/LAV]) are not necessarily ill. Most cases of AIDS from transfusion follow multiple transfusions to a premature or immunocompromised infant.

Infants with AIDS present clinically in a manner similar to patients with other immunodeficiency disorders: recurrent and frequent infections, opportunistic infection, failure to thrive, chronic diarrhea, developmental delay, lymphadenopathy and skin infection are frequent features. Features relatively unique to pediatric AIDS are recurrent parotitis and chronic lymphoid interstitial pneumonitis. The age of onset may vary from the first month of life to as long as five years after exposure. Most infants become symptomatic within the first year.

Laboratory abnormalities include lymphopenia, thrombocytopenia and abnormal chest roentgenograms. In contrast to other immunodeficiency disorders, patients usually have elevated serum immunoglobulins. The T-helper/T-suppressor cell ratio is usually reduced, but unlike that in adult patients may be elevated. This test should not be used to establish a diagnosis. Other immunologic studies show significant impairment of T-cell and B-cell immunity. The most important laboratory test is that of antibody to HTLV-III/LAV. Maternal transfer of immunoglobulin G antibody to HTLV-III/LAV occurs so that testing should be done only after 6 months of age. Isolation of HTLV-III/LAV in an infant younger than 6 months establishes direct infection. Diseases that require exclusion are primary immunodeficiency disorders, especially those associated with adenosine deaminase and nucleoside phosphorylase enzyme deficiency.

Not all children who are antibody-positive have clinical features of AIDS or laboratory abnormalities suggesting immunodeficiency. As the incubation period may exceed five years, these children should be followed carefully for the development of symptoms, immunodeficiency or both. Once the diagnosis is established, appropriate therapy may be instituted, including prophylactic trimethoprim-sulfamethoxazole to prevent *Pneumocystis carinii* pneumonia and intravenous administration of immune globulin to prevent both viral and bacterial infections.

A controversial area of pediatric AIDS relates to public health considerations. There is no evidence of casual spread of HTLV-III/LAV from infected persons to noninfected persons. Direct inoculation of the virus (blood transfusions) or sexual contact is required. Nevertheless, children with AIDS, or those who are antibody-positive but asymptomatic, have been ostracized and prevented from attending school. A physician caring for a child with AIDS may be deeply involved in educating parents, public health agencies, school boards and the public.

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Long-term Outcome in Infants With a Very Low Birth Weight

With the advent of highly specialized obstetric and neonatal management for high-risk mothers, fetuses and neonates, neonatal mortality has decreased sharply in the past two decades. The major contribution has been the increased survival in very-low-birth-weight infants (less than 1,501 grams). In the period 1950 to 1960, two thirds of the very-low-birth-weight infants died. An infant who weighed less than 1,001 grams at birth had less than a 5% chance of survival. On follow-up, more than half of the surviving very-low-birth-weight infants were found to have significant physical, neurologic and developmental handicaps.

Today many centers report survival rates of 80% in infants with birth weights of from 1,001 to 1,250 grams and 90% in infants weighing 1,251 to 1,500 grams. Are a greater number of very-low-birth-weight infants now surviving only to increase the number of handicapped persons in our society? Apparently not. The infants with birth weights of 1,001 to 1,500 grams, who represent more than 70% of the total very-low-birth-weight group, do well, with less than 10% showing major problems at preschool age. It would appear that perinatal and neonatal management today has proved successful in reducing both mortality and morbidity in infants who weigh more than 1,000 grams at birth.

On follow-up the problems that affected the larger very-low-birth-weight survivors born 25 years ago are now found in the very tiny infants with birth weights of less then 1,001 grams. Recent follow-up programs of infants born in the late 1970s and early 1980s report a high incidence (40% or greater) of major neurodevelopmental handicaps among survivors with birth weights from less than 800 grams. A resurgence of retrolental fibroplasia with severe visual impairment or blindness is reported in more than 10% of the very tiny infants weighing less than 1,000 grams. Because these infants account for less than 0.4% of all live births, however, they represent a very small total number. Mortality has been reduced in these fragile complicated infants but morbidity remains unacceptably high.

The present challenge is the development of perinatal and neonatal management techniques that result in far fewer physically, neurologically and developmentally handicapped children among those born weighing less than 1,001 grams.

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Human Growth Hormone

Distribution of the human growth hormone (hGH), obtained from the pituitary glands of cadavers, was suddenly discontinued in April 1985 following reports that three adults, ages 21 to 34, who received growth hormone treatment beginning in the 1960s had died of Creutzfeldt-Jakob disease, a slow virus infection of the brain. The disease was confirmed by pathologic examination of two patients; the other patient had clinical features of the disease but an autopsy was not done. Only growth hormone-deficient children with hypoglycemia were continued on treatment until a biosynthetic growth hormone was approved by the Food and Drug Administration in October 1985. Although current processing techniques are thought to destroy the virus, it is highly contagious and very resistant to chemical processing. Studies using animals are currently in progress to determine whether the virus can be transmitted in recent growth hormone preparations.

Contamination of hGH preparations with the Creutzfeldt-Jakob virus occurs in several ways: Human growth hormone was previously prepared from as many as 20,000 pituitary glands, yet patients with chronic neurologic diseases were not excluded from the donor population. Because the incubation period of Creutzfeldt-Jakob disease is long, some patients infected with the virus may have died before they were clinically symptomatic, and their infected pituitary glands were included in the donor pool. The incidence of the disease is one per million worldwide; in persons younger than 40, the incidence is .01 per million. Thus, the occurrence of three patients with Creutzfeldt-Jakob disease treated with hGH within one year strongly suggests that the infection was acquired from contaminated hGH preparations.

Although growth hormone-deficient children with hypoglycemia were continued on therapy, no treatment was available for many other growth hormone-deficient children until a biosynthetic human growth hormone (Protropin, Genentech Laboratories, South San Francisco, California) was approved in October 1985. Protropin, synthesized by recombinant DNA techniques using a strain of *Escherichia coli*, contains 191 amino acids identical to hGH plus methionone at the *N*-terminal portion of the molecule. In clinical trials with Protropin in growth hormone-deficient children, linear growth rates were comparable to those in children receiving pituitary-derived hGH. Of 84 children treated with Protropin, antibodies to the growth hormone developed in 40%, but this did not interfere with growth except in one child.

The primary indication for treatment with synthetic human growth hormone is growth hormone deficiency shown by subnormal growth hormone response to two provocative tests. Some very short children growing less than 4.5 cm per year but with normal growth hormone levels in response to provocative stimulation have also responded to the use of human growth hormone, but indications for treatment are not well defined. The possible risks and benefits of treatment with hGH in other children with short stature is not yet known.

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Current Therapy for Asthma—New Inhalants

Inhalation therapy has increased in importance for the treatment of asthma as more effective drugs have become available and newer methods and techniques of delivery have been developed.

Several new β-adrenergic bronchodilator aerosol drugs are available for the treatment of asthma. One of the first β_2-agonists developed for asthma was isoproterenol, which has a short duration of activity and both β_1- and β_2-specific effects. In a search for more selective and longer acting drugs, new agents have been developed by modifying the chemical structure of the basic catecholamine molecule. Isoetharine has a duration of activity similar to that of isoproterenol, but is more β_2-selective. Noncatecholamine inhalants were subsequently developed and include metaproterenol, albuterol, terbutaline and bitolterol. These agents have a somewhat slower onset of action but a much longer duration of activity and greater β_2-selectivity than isoproterenol. Terbutaline, albuterol and bitolterol may be somewhat more bronchoselective and have a longer duration of activity than metaproterenol.

Although the new β-agonists are safer than their predecessors, they can cause adverse effects. Adverse cardiac effects can also be intensified by the concomitant use of theophylline, which can stimulate endogenous catecholamine release. Large doses of inhaled adrenergic agents alone or with theophylline can lead to hypopotassemia, thus greatly increasing the chance of cardiac arrhythmias. Paradoxical increases in airway obstruction and aggravation of hypoxemia reported following isoproterenol sulfate inhalations has not been reported with the newer, more selective agents. Sulfites, used as antioxidants, are present in bronchodilator solutions and have recently been found to cause bronchoconstriction in some susceptible patients with asthma. These substances, however, are not present in metered-dose inhalers or in the individual-dose vials of metaproterenol sulfate solution. With respect to tachyphylaxis, it is felt that the more selective β-agonists can be used for prolonged periods of time without fear of reducing bronchodilator activity.

One third to one half of patients use an improper technique when using metered-dose inhalers, and about 14% to 16% are unable to learn even after careful instruction. A new technologic development uses a spacer attachment consisting of a tube, cone or holding chamber between the actuator of the metered-dose inhaler and the patient's mouth. These devices not only improve delivery of the medication to the lungs and decrease oropharyngeal deposition but, of greatest importance, overcome the need for synchronization between firing the aerosol and inhaling. Large-volume spacers or reservoirs (500 to 1,500 cm) equipped with valves are particularly valuable in this respect. Several types are now available in this country, including Inhal-Aid, InspirEase, Breathancer and Aerochamber. Spacers may be of particular value for administering inhaled corticosteroids by reducing the incidence of oral candidiasis or dysphonia. Beclomethasone, triamcinolone and flunisolide are corticosteroids that can be prescribed for use as aerosols by metered-dose inhaler, as can cromolyn sodium (Intal Spinhaler); the triamcinolone inhaler is available with an attached spacer.

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Oral Rehydration Therapy for Diarrhea

Oral rehydration therapy for diarrhea uses the principle of glucose-facilitated intestinal absorption of sodium and water to rapidly return a child to a euhydrated state. When successful, rehydration can be accomplished in 6 to 12 hours, obviating the need for parenteral therapy. Recent interest in oral rehydration therapy developed because of the need to find an effective, safe and practical treatment of dehydration associated with cholera in areas where parenteral therapy was unavailable. Use of the World Health Organization (WHO) oral rehydrating solution resulted in a dramatic decrease in mortality. Global acceptance of oral rehydration therapy is slowly evolving. Children have a prodigious capacity to absorb sodium-containing fluid at rates exceeding 15 ml per kg per hour. Intestinal sodium absorption can be facilitated in the presence of 2.0% to 2.5% glucose, but the glucose-linked sodium transport system becomes saturated with glucose concentrations greater than 3%, which may result in increased diarrhea due to intestinal hyperosmolarity. Fasting has a negative effect on sodium and water absorption.

Conventional therapy for diarrhea resulting in dehydration is to withhold oral fluids and replace deficits intravenously over 24 hours. Oral intake of fluids is usually reinstituted with small, frequent feedings of clear liquids followed by diluted formula. While effective and relatively safe, this regimen is empirical, expensive and disregards the capacity of the intestine to absorb fluid and electrolytes despite concomitant stool losses.

In contrast, oral rehydration therapy uses glucose to facilitate intestinal salt and water absorption, deficits being replaced over 6 to 12 hours. Sucrose has been substituted in some regimens because of its universal availability and diminished cost. Its efficacy approaches that of glucose despite dependency on intestinal disaccharidases for hydrolysis. Rice powder that contains glycine plus amylose and amylopectin (which can be hydrolyzed to glucose) will significantly lower stool output and duration of diarrhea when compared with the standard 2% glucose solutions. Homemade sugar-salt solutions are not recommended because of the risk of inappropriate reconstitution.

The WHO oral rehydrating solution contains sodium, 90 mEq per liter; potassium, 20 mEq per liter; chloride, 80 mEq per liter; bicarbonate, 30 mEq per liter, and glucose, 111 mmol per liter. The composition of this soluution approximates conventional mixtures used to treat moderate dehydration intravenously except in its glucose concentration. The volume of fluid to be given orally or via nasogastric tube in the first six hours is derived from the estimated percent dehydration (50 to 100 ml per kg), maintenance needs (25 ml per kg per six hours) and projected ongoing losses (12 ml per kg per six hours). Two thirds of the total volume is replaced over four hours with the WHO oral rehydrating solution. The final third is given as free water over the next two hours to allow for renal excretion of excess solute. Alternatively, 100 ml per kg of the WHO solution may be given for four hours, followed by 50 ml per kg of water during the next two hours.

Subsequent oral therapy should provide for maintenance fluid and electrolyte requirements and for anticipated ongoing losses. Use of the WHO oral rehydrating solution during this maintenance phase is not recommended. A solution that contains about 30 to 50 mEq per liter sodium, 20 to 30 mEq per liter potassium and 2% glucose should be used for no more than 24 hours. Return to a non-lactose-containing formula should commence within 24 hours. Breast-feeding should be continued throughout the diarrhea.

Traditionally pediatricians have been warned against rapid rehydration, particularly in children with hypernatremia, to avoid seizures due to intracellular influx of water. Although oral rehydration therapy results in a more rapid fall in serum sodium levels when compared with intravenous therapy, the incidence of seizures is not increased. In one study, the risk of seizures was related to the initial serum sodium concentration rather than to the rate of fall in serum sodium concentration. In addition, the occasional hyponatremia measured after oral rehydration therapy seems to be clinically insignificant. In children with hypovolemic shock, this therapy should only be used after adequate volume expansion with intravenous fluids and when the child is alert enough to cooperate with the regimen. Vomiting is not a contraindication to oral rehydration therapy, as rapid restoration of volume seems to diminish vomiting. Failure can be anticipated if the loss exceeds 10 ml per kg per hour and in children with paralytic ileus, in those with known glucose or sucrose intolerance or when purge rates exceed 10 ml per kg per hour.

Despite these possible obstacles, oral rehydration therapy obviates the need for the intravenous administration of fluids in 75% to 95% of children treated for dehydration. Appropriate use and careful monitoring will assure the safety of oral rehydration, which represents a physiologic, noninvasive and potentially cost-effective alternative approach to the conventional management of diarrhea in childhood.

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Surfactant Treatment of the Respiratory Distress Syndrome

Soon after the identification of dipalmitoylphosphatidylcholine as the principal compound in pulmonary surfactant and the recognition in 1959 that infants who died of the respiratory distress syndrome had abnormal surface properties of the lungs, aerosols of this compound were tried unsuccessfully as treatment for this disorder. In the 1970s, however, a sound scientific basis for treatment with natural surfactant was established in preterm animals. In 1980 the results of the first uncontrolled trial of the use of surfactant prepared from beef lung were published. Since then 15 studies have been published, of which 6 have been controlled, radomized clinical trials. While many of these have shown remarkable responses to surfactant, others have shown no effects, depending on the surfactant chosen for the studies.

Natural pulmonary surfactant is a complex mixture of phospholipids, neutral lipids and at least two classes of surfactant-specific proteins. Surfactant is present in the airways and alveoli as aggregates of various sizes, the most surface active being the largest. These large surfactant aggregates will rapidly absorb to and spread on an air-water interface to establish an equilibrium surface tension of about 25 dynes per cm. On dynamic compression of the surface film, surfactant will lower the surface tension to values less than 10 dynes per cm. These surface properties can be reproduced using carefully resuspended lipid extracts of natural surfactant that contain less than 1% protein. The technique of resuspension is critical to surface behavior, as the composition of a surfactant is less important than the aggregate form of the lipids in suspension. Further, synthetic lipid surfactants can have in vitro properties similar to natural surfactant, yet be inactive in vivo. A surfactant for clinical use is not a traditional single-component pharmaceutical; rather, surfactant is a mixture of compounds whose surface physical properties in vitro may not be sufficient for in vitro function. Responses to a surfactant may be predicted only from the effects on surfactant-deficient premature lungs.

Based on sound experiments in animals, two strategies for clinical trials have been used. In the initial pilot trial, ventilator-dependent infants with severe respiratory distress syndrome were treated with tracheal instillation of suspensions of surfactant in saline. In a number of subsequent trials, workers have tried to prevent the respiratory distress syndrome by treating at-risk infants with surfactant in the delivery room. Infants treated with synthetic surfactants have no immediate improvement in lung function. In contrast, infants treated with animal or human surfactants may have immediate improvement in lung function. Following injection of surfactant into the airways of infants with severe respiratory distress syndrome, a surfactant response is characterized by a rapid decrease in oxygen requirements. In some trials, the ventilatory support could be decreased as well. The response was better and more prolonged when treatment was given as soon as possible after initiating ventilation.

Infants treated in the delivery room have a lower incidence and severity of the respiratory distress syndrome than control infants. Overall, treatment at birth decreases the oxygen requirements and ventilator support variables of the treated infants relative to control infants. When the groups treated at birth or after the onset of the respiratory distress syndrome are combined, pneumothorax is decreased from 28% in control to 12% in treated infants, pulmonary interstitial emphysema is decreased from 38% in control to 6% in treated infants and bronchopulmonary dysplasia is decreased from 46% in control to 33% in the surviving treated infants. Mortality was 31% in control infants and 12% in treated infants. Thus, surfactant treatment lowered the incidences of the major pulmonary complications of the respiratory distress syndrome and mortality. Incidences of other nonpulmonary complications of prematurity such as intraventricular hemorrhage, necrotizing enterocolitis or severe retinopathy of prematurity either were unchanged or decreased numerically but not statistically.

Surfactant seems to be a major advance in the treatment of the respiratory distress syndrome. Surfactants tested to date have been "homemade" and are not licensed for clinical use. Standardized surfactant preparations are being evaluated in clinical trials for licensure by the Food and Drug Administration (FDA). At present, a physician can treat infants only by preparing a surfactant and obtaining the necessary FDA permission for experimental drug use.

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Abstracts by Residents and Fellows

AMERICAN COLLEGE OF PHYSICIANS, CONNECTICUT CHAPTER

FOREWORD: On September 12, 1986, the Connecticut Chapter of the American College of Physicians held its regional meeting at Norwalk Hospital. Part of the scientific session included presentations of papers by Associates of the College, which were well received by the audience. Each year, medical residents and fellows throughout the state prepare papers, usually case reports, and submit abstracts for consideration. Those authors who are selected to present their papers at the regional meeting are awarded cash prizes. This year there were 17 abstracts submitted, which have been printed below.

Joseph P. Cleary, M.D., Associate Program Director, Residency Program, Department of Medicine, Norwalk Hospital, Norwalk, CT.

Bilateral Pneumothoraces and Pneumoperitoneum Following Esophageal Intubation

JEFFREY J. BILOTTA, M.D., Department of Internal Medicine, Stamford Hospital, Stamford, CT.

Esophageal rupture associated with usage of the Sengstaken-Blakemore tube for bleeding esophageal varices is a known complication of this procedure and may occur if the gastric balloon is inflated while improperly positioned in the esophagus, or if the gastric balloon becomes situated in the esophagus as a result of migration, increased traction from external forces, or from forcible withdrawal by an uncooperative patient. We describe an unusual, fatal case of bilateral pneumothoraces and pneumoperitoneum occurring immediately following inflation of a Sengstaken-Blakemore gastric balloon in a patient with bleeding esophageal varices. A review of the therapy and complications of esophageal tamponade for bleeding esophageal varices and portal venous hypertension is presented and ideas regarding improvement in the outcome of this procedure are advanced.

Treatment of Mediastinal and Subcutaneous Emphysema with Helium and Oxygen

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The use of high concentrations of oxygen (i.e., $> 50\%$ oxygen) to accelerate the resorption of subcutaneous and mediastinal emphysema has been described. The mechanism of increased resorption involves and increased tissue-to-blood nitrogen gradient. However, use of such concentrations of oxygen involves the risk of oxygen toxicity.

We describe a patient with chronic mediastinal and subcutaneous emphysema who responded to a nontoxic mixture of helium and oxygen. We believe the mechanism of action is similar to that of high oxygen concentrations, i.e., accelerated nitrogen washout.

Helium-oxygen mixtures may offer an advantage over high oxygen concentrations in the treatment of mediastinal and subcutaneous emphysema, particularly if chronic air leak is suspected.

The Benign Course of Diverticulitis Associated with Hepatic Portal Venous Gas

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Hepatic portal venous gas (HPVG) was first described in 1955, with over 70 cases reported since then. The association of hepatic portal venous gas with catastrophic abdominal events has led to the recommendation that emergency laparotomy be done when hepatic portal venous gas is found.

We report a patient with diverticulitis and hepatic portal venous gas found on ultrasound and CT scan, who was treated medically. He was clinically stable with complete resolution of the hepatic portal venous gas on CT scan.

This is the fifth case of diverticulitis and hepatic portal venous gas reported in the literature and the first one treated medically. The overall mortality of this group is 0%, compared to 75% described in previous literature. This difference may be attributed to the fact that hepatic portal venous gas can now be diagnosed by CT scan allowing smaller amounts of air to be detected. The clinical significance of hepatic portal venous gas in a stable patient may be different from that associated with a catastrophic abdominal event.

We conclude that conservative therapy may be adequate for clinically stable patients with hepatic portal venous gas and underlying diverticulitis.

Eosinophilic Meningitis in a Cambodian Female

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Cerebrospinal fluid (CSF) eosinophilia occurs in less than 3% of lumbar puncture samples. Etiologies include infections, most frequently helminthic, neoplasms, hypereosinophilic syndrome, multiple sclerosis, and foreign bodies. The following is a description of a case of eosinophilic meningitis.

A 26-year-old Cambodian female presented with acute diarrhea associated with headache, photophobia, nuchal rigidity, and diplopia. Physical examination was significant for low grade temperature and a positive Brudzinski sign. CSF analysis showed a leukocytosis (1400 to 1450) with an eosinophilic pleocytosis (11% to 16%), elevated protein (147), and decreased glucose. Peripheral eosinophil count was 29%. CT of the head was negative.

Serology was positive for cysticercosis with stools positive for *Strongyloides stercoralis* and *Clonorchis sinensis*. Subsequently, the patient was started on a course of praziquantel and thiabendazole. The hospital course was uncomplicated.

The abnormal finding of eosinophils in the CSF is a rare occurrence in the continental United States, but is much more common in the South Pacific. With the increased immigration of Southeast Asian peoples into the United States, the differential diagnosis of eosinophilic meningitis is an important one that must be kept in mind especially as effective treatment for cysticercosis is available.

Pancreatic Tuberculous Abscess Mimicking Cancer

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A patient presented with a three week history of epigastric pain and fever. Initial evaluation revealed a retrogastric mass and para-aortic adenopathy. The patient was treated with exploratory laparotomy and extensive drainage, followed by antituberculous antibiotics when mycobacteria were identified.

A 31-year-old Haitian male presented with two weeks of persistent epigastric pain and fever. He denied exposure to tuberculosis, hemoptysis, weight loss, or previous hospital admission. He had had left lumbar pain for two years related to heavy lifting. He denied homosexuality or IV drug use. On physical exam he was febrile, had small bilateral axillary lymphadenopathy, bilateral gynecomastia, a II/VI systolic murmur, clear lungs, epigastric tenderness with a 10cm liver span. He had normal genitalia, guaiac negative stools, and a nonfocal neurological examination. Abdominal CT showed a retrogastric mass and multiple para-aortic lymph nodes.

With a working diagnosis of an intra-abdominal abscess or lymphoma, the patient underwent an exploratory laparotomy which revealed a large pancreatic abscess. Subsequent AFB smears of the material were positive. The patient improved on antituberculous medication. Cultures ultimately revealed *Mycobacterium tuberculosis*.

This case illustrates both the common presentation of the abdominal abscess and the rare pancreatic tuberculosis mimicking cancer. As reviewed by Stambler et al., pancreatic involvement is unusual in miliary tuberculosis, and focal pancreatic tuberculosis is even less common. Pitlik et al. reviewed 26 patients with initial diagnosis of cancer who, after further studies, showed different forms of tuberculosis.

The case also raises questions involving the pathophysiology of abscess formation, tuberculous infection, and immunosuppression.

Gastric Volvulus with Acute Left Pleural Effusion

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Acute and chronic gastric volvulus are rare but may have a significant mortality (30-50%). Symptomatic volvulus classically presents as vomiting followed by retching and inability to vomit, epigastric distension and inability (or difficulty) to pass a nasogastric tube. Prompt differentiation from other diseases and surgical intervention are crucial, as illustrated in the following case.

A 71-year-old man with a history of a large hiatal hernia and previous duodenal ulcer complained of a prolonged feeling of upper abdominal pressure. Physical examination revealed diminished breath sounds at the lung bases, hypoactive bowel sounds, and epigastric tenderness. EKG showed T-wave flattening anterolaterally. Partial relief of epigastric pressure was obtained with sublingual nitroglycerin. The following day cardiac enzymes were normal, but he developed progressive dyspnea, a marked left shift of his WBC, and a new left pleural effusion. Heme positive stool, absent bowel sounds, and persistent epigastric tenderness prompted placement of a nasogastric tube which drained 500cc of green fluid. Emergency GI series suggested gastric volvulus within the thorax. At surgery an incarcerated volvulus and a penetrating duodenal ulcer were found in the chest. Partial gastrectomy and duodenectomy, vagotomy, and diaphragm closure were performed with good results.

Review of this patient's previous UGI series revealed gastric volvulus misinterpreted as a large hiatal hernia. We conclude that early surgical intervention in gastric volvulus should be considered to prevent serious complications.

Relapse of Encephalitic Symptoms Following Successful Therapy of Herpes Simplex Encephalitis with Acyclovir

Case Report and Review of the Literature

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A 19-year-old male presented with symptoms consistent with herpes simplex encephalitis (HSE) and subsequent brain biopsy demonstrated HSV-a. The patient was treated successfully with a 10 day course of acyclovir, but 12 weeks following the initial therapy symptoms recurred. A second course of acyclovir again produced remission of symptoms. Recent reports in the literature have shown significant advantages of acyclovir therapy over adenine arabinoside (Ara-A) in reducing the morbidity and mortality associated with HSE. Recurrences of encephalitic symptoms within several months of the initial acute infection have been reported following the use of Ara-A and attributed to relapsing infection or to post-infectious encephalomyelitis. A case of HSE relapse following inadequate initial therapy with acyclovir and a case of post-infectious encephalomyelitis following therapy with acyclovir have been previously reported. In both of these cases, symptoms recurred within two weeks of finishing the initial course of therapy. This is the first reported case of recurrent encephalitic symptoms occurring several months after successful treatment of biopsy-proven HSE with acyclovir which responded successfully to a second course of intravenous acyclovir. The clinical course with response to acyclovir supports a diagnosis of relapsing HSE rather than post-infectious encephalomyelitis.

Right Ventricular Myocardial Infarction Complicated by a Right-to-Left Shunt and Paradoxical Embolism

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The incidence of a patent foramen ovale (PFO) in adults at autopsy is 27%. Consequently, a significant population may present with a potential interatrial shunt (IAS). This case report illustrates how a right ventricular myocardial infarction (RVMI) may present with an IAS resulting in a paradoxical embolism.

A 49-year-old man presented with shortness of breath and chest pain. Physical examination showed hypotension, venous distension and a clear chest. Laboratory data showed a large inferior wall MI, reduction of right ventricular function, normal left ventricular function, and refractory hypoxemia. Catheterization revealed marked elevation of right atrial pressures, and saline contrast echocardiography showed an IAS. Therapy included saline/vasopressor support and implantation of a pacemaker. Subsequently, the patient experienced a fatal cerebral embolus. Necropsy demonstrated fresh infarction of the posterior-inferior walls of the right and left ventricles, mural thrombus of the right atrium, thrombotic occlusion of the left internal carotid artery, and a PFO.

This case illustrates another complication of a large RVMI in the setting of a PFO. There are four published cases of RVMI complicated by an IAS but none with a paradoxical embolism. This case has important therapeutic implications, suggesting an additional role for thrombolytic therapy.

Bacillus Cereus Bacteremia in an Intravenous Drug Abuser

A Case Report and Review of the Literature

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Bacillus species, with the exception of *Bacillus anthracis*, are usually considered to be nonpathogenic. *Bacillus cereus* bacteremia is uncommon. However, it has recently been recognized as a complication of intravenous drug abuse. As the incidence of narcotic addiction rises, there has been an increase in the frequency of reported cases of *Bacillus cereus* bacteremia in intravenous drug abusers. Therefore, it is important to recognize that *Bacillus cereus* may no longer be dismissed as a significant pathogen. We report a case of *Bacillus cereus* bacteremia in a cocaine/heroin addict and a review of the world literature in English of *Bacillus cereus* bacteremia in intravenous drug abusers. Only ten previous cases of *Bacillus cereus* bacteremia have been reported in narcotic addicts.

The major points of these articles are that if *Bacillus cereus* is cultured, it may not be a contaminant; secondly, because of its peculiar antibiotic susceptibility pattern, it is difficult to treat. However, with appropriate antibiotic therapy, the infection can be managed successfully, especially in the patient who is not compromised in other ways. Of all Bacillus species, *Bacillus cereus* is, after *Bacillus anthracis*, the most likely to be pathogenic.

Evaluation and Treatment of Cushing's Syndrome in a Patient with Multiple Endocrine Neoplasia Type IIB

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A 25-year-old male was evaluated for Cushing's syndrome. In 1981 he was diagnosed as having multiple endocrine neoplasia syndrome, type 2b, with medullary carcinoma of the thyroid (MCT), characteristic facies, mucosal neuromas, and autonomic dysfunction secondary to ganglioneuromas. At that time, the MCT was incompletely resectable. Subsequent elevation of serum calcitonin indicated persistent tumor activity. Multiple evaluations for pheochromocytoma were negative.

In 1983 he developed mild diabetes and hypertension. Serum cortisols were elevated and did not suppress with dexamethasone. Mitotane and aminoglutethamide were both unsuccessful as therapeutic agents because of intolerable gastrointestinal side effects.

In 1985 the patient presented with worsening diabetes, hypertension, and stigmata of Cushing's syndrome. A dexamethasone suppression test showed no suppression with low dose and incomplete suppression with high dose dexamethasone, indicating ectopic ACTH production. Metyrapone at doses to three grams per day had no effect on urinary free cortisol (UFC). Ketoconazole was then tried to block steroid biosynthesis. Doses up to 800 mg per day had no effect. But a dose of 1200 mg per day resulted in normalization of UFC and 17-OH-0CS. Therapy was complicated by severe fungal cystitis unresponsive to amphotericin irrigation. Bilateral adrenalectomy was ultimately required for cure.

Legionnaires' Disease Masquerading as Pulmonary Embolus

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There is no immediate laboratory confirmation of the diagnosis of legionnaires' disease; therefore, it may readily be confused with other entities, particularly when the presentation has atypical features.

Ten days after admission for therapy of low back pain with bed rest and prednisone, a 42-year-old woman developed pleuritic chest pain and dyspnea. Physical examination was normal, and the chest x-ray showed a new, rounded, nodular left lower lung density. A perfusion lung scan showed a matched defect, and an angiogram showed abnormal vessels in the lower left lobe without a vascular "cut-off" or intraluminal defect. Heparin was begun. One day later she developed increased dyspnea, fever to 39° C and productive cough. Sputum Gram stain showed many PMNs and rare gram-negative rods. Heparin was stopped and tobramycin, cefamandol and erythromycin were begun. Her condition worsened and the x-ray showed left lower lobe consolidation and cavitation; sputum culture yielded *Legionella pneumophilia*. Antibody titers increased from 0 to 1:4096 on a convalescent specimen.

Nodular infiltrates represent an atypical radiographic manifestation of legionnaires' disease. This case illustrates that in the setting of high clinical suspicion of pulmonary embolism, an indeterminant lung scan and angiogram should alert the clinician to consider alternative diagnoses and therapy.

Chronic Thyroxine Ingestion Causing Thyroid Storm and Markedly Accelerated Thyroxine Turnover

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Factitious thyrotoxicosis is uncommon as is thyroid storm. There are only a handful of case reports of thyroid storm due to acute thyroxine overdose. We present a patient with thyroid storm due to chronic l-thyroxine ingestion. Thyroxine turnover is known to be accelerated in thyrotoxicosis but has not been measured in thyroid storm. With serial total thyroxine measurements we were able to calculate thyroxine turnover and half-life in this patient. A 66-year-old female seen in the emergency room for a fractured humerus was found to be tachycardic, tachypneic, febrile, and in congestive heart failure. History revealed she had been intentionally ingesting up to 900 mcg of l-thyroxine daily in a successful effort to lose 100 pounds. She was treated with propylthiouracil, dexamethasone, and iopanoic acid. Calculations revealed her total thyroxine turnover to be 25%/day and total thyroxine half-life to be 48 hours. Previous studies using labelled l-thyroxine have shown thyroxine half-life to range from 4-7 days in patients with thyrotoxicosis. Thyroxine turnover in thyroid storm may be faster than in thyrotoxicosis. This is the first reported case of thyroid storm due to chronic thyroxine overdose. The greatly accelerated thyroxine turnover calculated in this case raises the question of whether the turnover of other compounds in thyroid storm is greatly changed.

Angioimmunoblastic Lymphadenopathy

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The patient discussed in this report is a 50-year-old man who presented with a two year history of progressively worsening episodes of fever and urticaria. Except for the elevated temperature and the raised erythematous rash, the examination was positive only for generalized lymphadenopathy. The patient had an extensive initial workup that was unrevealing, including negative blood cultures and a lymph node biopsy showing nonspecific inflammatory changes. The patient ultimately developed hepatosplenomegaly and an interstitial pulmonary infiltrate, with a repeat lymph node biopsy showing immunoblasts and a proliferation of small vessels consistent with the diagnosis of angioimmunoblastic lymphadenopathy. Lung biopsy revealed usual interstitial pneumonitis. He was treated with prednisone and has shown an excellent clinical response.

This case demonstrates the difficulty in diagnosing angioimmunoblastic lymphadenopathy, as well as the systemic nature of this process. An unusual manifestation in this case was that of the interstitial pneumonitis.

Splenic Infarction in a Patient with Systemic Lupus Erythematosus

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The most common abnormality of the spleen in systemic lupus erythematosus is splenomegaly, which correlates with the hematocrit and is thought to be secondary to the hemolytic anemia. There have been reports of hyposplenism in patients with lupus, and the proposed mechanism is repeated small splenic infarcts secondary to the vasculitis.

The case described is a 25-year-old female with a three year history of systemic lupus erythematosus. She presented with complaints of seven days of sharp left upper quadrant abdominal pain, arthralgias, and intermittent fever. She was afebrile, and had an unremarkable physical examination, except for left upper quadrant tenderness. The spleen was not palpable. The laboratory values were unchanged from her baseline, and specifically failed to reveal an exacerbation of her lupus. A CT scan showed a 4.5 cm area of diminished attenuation in the spleen, which was consistent with an infarct. The patient was managed with bedrest and analgesics, and improved. However, her pain recurred, again in the absence of clinical and laboratory evidence of active lupus, or another etiology of a splenic infarct. The appropriate management of the patient was controversial: whether to treat her for active lupus, recommend splenectomy, or simply to observe her. The case illustrates the need to include a splenic infarct in the differential diagnosis of left upper quadrant abdominal pain, and that a large splenic infarct can complicate systemic lupus erythematosus.

Splenic Infarction in an Intravenous Drug User

JAMES J. VREDENBURGH, M.D., Department of Medicine, St. Francis Hospital, Hartford, CT.

Splenic infarction is an uncommon cause of abdominal pain. Many conditions predispose to splenic infarction, including endocarditis, severe atherosclerosis, and hemoglobinopathies.

A 20-year-old intravenous drug user presented with fever, and left upper quadrant abdominal pain. He had no peripheral stigmata of endocarditis and a 1/6 early systolic ejection murmur. The spleen was not palpable, and his stool was guaiac negative. The blood cultures remained negative, and the echocardiogram showed no valvular vegetations. The liver-spleen scan revealed multiple filling defects in the spleen, which were confirmed by CT scan. He defervesced with antibiotics, and his pain improved. However, the pain and fever intermittently returned, and a decision was made to perform a splenectomy. The operative specimen showed a 12x6 cm infarct and two 1 cm infarcts. He had an uneventful postoperative recovery.

The case presented some important issues and remained a pathopysiologic puzzle. Splenic infarcts must be differentiated from other conditions, such as splenic abscess or perforated viscus, which require surgery. The patient was at risk for endocarditis, with a septic embolus producing a splenic abscess, but the physical examination, cultuers, and echocardiogram failed to document endocarditis or an abscess. He had nothing to suggest atherosclerosis, a hemoglobinopathy, trauma, or a vasculitis, as an etiology of the splenic infarct. The case illustrates that a splenic infarct must be included in the differential diagnosis of a patient with left upper quadrant abdominal pain, even in the absence of predisposing conditions.

A Duodenal Somatostatinoma

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A 64-year-old white female was admitted to Hartford Hospital with four weeks of intermittent fever and right upper quadrant pain. Her past medical history was notable for a cholecystectomy in 1954 and the recent onset of Type II diabetes mellitus in 1984. Physical examination was remarkable for right upper quadrant tenderness and hemocult positive stools. An ultrasound of the right upper quadrant revealed dilatation of the common bile duct with prominence of the intrahepatic and pancreatic ducts. Laboratory values were consistent with biliary obstruction. An ERCP was attempted which revealed a multilobular, friable, ampullary mass; cannulation could not be achieved. Biopsy specimens revealed this mass to be a malignant neuroendocrine tumor of the duodenum. A CT scan of the abdomen was normal. The patient underwent a Whipple resection. Immunohistochemical techniques determined the tumor to be an APUDoma of foregut origin with immunoreactivity for somatostatin. The patient's post operative course was unremarkable. Her diabetes is now easily controlled on a low dose oral hypoglycemic agent.

Somatostatinoma is a rare tumor with fewer than 30 cases reported in the world literature. Larsson reported the first case of somatostatinoma in 1977. His patient had a somatostatinoma of the head of the pancreas. He described the "Somatostatinoma Syndrome" of diabetes mellitus, cholelithiasis, and steatorrhea. Duodenal somatostatinomas are generally hormonally inactive thus making the diagnosis elusive until specimens can be obtained for pathology. The improvement in this patient's glucose tolerance since surgery may identify this as a case of a hormonally active somatostatinoma.

Clinical Comparison of H_2-Antagonists

KAREN SMITH, R.PH. AND CATHERINE CRISP, PHARM.D.

Introduction

Cimetidine and ranitidine are competitive histamine-2 receptor antagonists whose primary effect is due to histamine antagonism of the gastric parietal cells which prevents the secretion of gastric acid and pepsin.[1-3] Ranitidine is 4-10 times more potent than cimetidine in inhibiting gastric acid secretion.[2,4-6]

Both these drugs are indicated for the short-term treatment of active duodenal ulcers, active benign gastric ulcers, pathological hypersecrtory states (i.e. Zollinger-Ellison syndrome) and for the prevention of recurrence of duodenal ulcers.[7,8] Only ranitidine has FDA approval for the treatment of reflux esophagitis.[8]

Clinical Efficacy

In clinical trials, ranitidine has been shown to be as effective as cimetidine in the treatment and prevention of gastric and duodenal ulcers. In patients with active duodenal ulcer, 50mg IV ranitidine q6-8hrs maintained the gastric pH at or above 5.0 for a longer time period than 300mg IV cimetidine q6hrs.[9] In one clinical trial, four weeks of oral ranitidine (150mg twice daily) was compared to oral cimetidine (200mg TID and 400mg at bedtime) in patients with active duodenal ulcers. The healing rates observed were 78% and 84%, respectively.[10] Other clinical trials confirm these response rates.[11-13]

There are no comparative studies of rantidine and cimetidine for the treatment of reflux esophagitis. However, in two double-blind clinical studies, oral ranitidine 150mg BID was effective in relieving symptoms of pain and producing endoscopic healing (i.e. decreased inflammation, healing of ulcerations) in 60% of the patients.[14,15] Cimetidine has been shown to be minimally effective for the treatment of esophageal reflux, with no improvement in endoscopic esophageal appearance.[16-18]

Ranitidine has also been successfully used to treat patients who have failed cimetidine therapy. Eight patients with Zollinger-Ellison syndrome who were not healed on 2-3g oral cimetidine, or who had been taken off therapy due to intolerable adverse effects, were successfully controlled with 600-900mg oral ranitidine per day.[8] In another report, three patients with life-threatening gastric hypersecretion states resistant to high doses of cimetidine responded to ranitidine therapy.[19]

Adverse Drug Reactions

Although similar in their mechanism of action, ranitidine and cimetidine differ in their incidence of adverse drug reactions. In clinical practice, the incidence seems to occur more often with cimetidine than ranitidine.

Side Effects

The most frequently reported side effects for both cimetidine and ranitidine are gastrointestinal problems including diarrhea, nausea, vomiting, and constipation.[20] In one prospective survey of over 9000 patients treated with cimetidine, there was an overall adverse reaction incidence of 4.2%; 2.1% of which were gastrointestinal complaints.[21] In another study involving more than 5000 patients treated with ranitidine, the most common complaint was headache (2-3%), with a less than 1% incidence of gastrointestinal side effects.[22] Cimetidine readily crosses the blood brain barrier and several central nervous system (CNS) toxicities have been reported including somnolence, slurred speech, dizziness, confusion, agitation, hallucinations, depression, and anxiety.[7,21] It appears that patients who are elderly, have hepatic and/or renal dysfunction or who are receiving higher than recommended cimetidine doses may be at greater risk for developing these adverse effects.[1] The CNS distribution of ranitidine is minimal and consequently, the incidence of CNS toxicity has been reported to occur less frequently.[1,20,23]

Cimetidine also adversely effects the endocrine system causing impotency and gynecomastia in select patients.[21] These effects are secondary to the binding of cimetidine to androgen receptors causing an elevated basal level of testosterone.[1] Most of the patients who develop this reaction are males who have been treated with long-term, high dose cimetidine therapy for Zollinger-Ellison syndrome. Treatment of these patients with ranitidine has,

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in most cases, reversed this adverse reaction.[22] Unlike cimetidine, ranitidine lacks affinity for androgen receptors.[24] There have been case reports of ranitidine causing adverse effects of the endocrine system, but the occurrence is much more common with cimetidine therapy.[22,25]

Both ranitidine and cimetidine can cause an elevation of serum prolactin in males.[22] This effect has only been seen with bolus IV administration of either drug.[20,22] Neither drug causes chronic hyperprolactinemia when administered orally. Additionally, other reports implicate both agents in suppression of other endocrine hormones including vasopressin and, with long-term oral therapy, aldosterone secretion. The clinical significance of either of these effects is uncertain.[22]

Other idiosyncratic adverse effects have been reported for both cimetidine and ranitidine. These are rare and include reports of alopecia, reversible arthralgias, hematopoietic changes, hepatic and renal changes and exacerbation of glaucoma.[20,26] There have been reports of bradycardia occurring after rapid administration of both ranitidine and cimetidine.[26,27]

Drug Interactions

Cimetidine and ranitidine differ greatly in the types of drug-drug interactions that have been reported. Cimetidine binds directly to the cytochrome P-450 enzyme system in the liver and thereby inhibits oxidative metabolism. It may also reduce hepatic blood flow which can interfere with the clearance of some drugs.[20,26] There is potential for toxicity when cimetidine is administered concommitantly with warfarin, diazepam, chlordiazepoxide, phenytoin, propranolol (and other beta-blockers), lidocaine, metronidazole, morphine and theophylline.[20,28,29] (See Table 1) Ranitidine, on the other hand, binds much less to the P-450 enzymes.[21] Although ranitidine also decreases hepatic blood flow (measured as a change in clearance of indocyanine green) and potentially could interfere with the clearance of drugs, clinically this interaction is not significant.[20]

Table 1

DRUG INTERACTIONS WITH CIMETIDINE

1. Mechanism: Inhibition of the cytochrome P-450 enzymes in the liver which may lead to toxicity of these drugs:

Caffeine Chlordiazepoxide Diazepam
Ethanol Imipramine Metronidazole
Nifedipine Phenytoin Propranolol
Theophylline Warfarin

2. Mechanism: A decrease in liver blood flow may decrease the clearance and thus enhance toxicity of these drugs:

Lidocaine Morphine Theophylline
Verapamil(IV)

In summary, the incidence of adverse drug reaction for either drug is low. However, cimetidine appears to be associated with more adverse central nervous system and endocrine abnormalities than ranitidine. Because of better binding to microsomal liver enzymes, there is a greater potential for clinically significant drug interactions to occur with cimetidine than with ranitidine.

Dosing

Although ranitidine and cimetidine have similar elimination half-lives,[1,6,29] their durations of action are quite different (duration of 50% inhibition of pentagastrin-stimulated acid secretion [IC50] is 8 hours and 2.5 hours, respectively).[1] Therefore, ranitidine may be administered less frequently than cimetidine. (See Table 2.)

Table 2

COST OF H2-ANTAGONIST DOSING AT HARTFORD HOSPITAL

Drug	*Dosing Regimen*	*Daily Cost to Hospital+*
I. Parenteral		
Ranitidine	50mg q12hrs	$9.78
Ranitidine	50 mg q8hrs	$14.81
Cimetidine	300mg q6hrs	$19.22
Cimetidine	300mg q4hrs	$28.35
Cimetidine	300mg q8hrs*	$15.58
II. Oral: Treatment		
Ranitidine	150mg BID	$1.62
Ranitidine	300mg qhs	$1.62
Cimetidine	300mg q6hrs	$1.56
Cimetidine	800mg qhs	$1.41
III. Oral: Maintenance		
Ranitidine	150mg qhs	$0.81
Cimetidine	400mg qhs	$0.71

+ Includes cost of administration for parenteral agents.
* New dosing regimen recently approved by FDA.

Initially, dosage regimens of H2-antagonists were designed to produce maximum suppression of gastric acid secretion for 24 hours. It has since been shown that for most hypersecretory states (i.e. duodenal ulcer), the time of high acid output is at night. Subjects with duodenal ulcers secrete 3-20 times more acid during a 12 hour period at night than do normal subjects (60-70mEq HCl vs. 10-20mEq HCl).[30]

The tendency now is to treat duodenal ulcers with a single large night-time dose of an H2-antagonist. A number of clinical studies have demonstrated efficacy of a single nocturnal dose, without an increased incidence of adverse effects. For treatment of active duodenal ulcer, the recommended night-time dose is 300mg of ranitidine and 800mg of cimetidine.[30,31,32-34] For prevention of ulcer recurrence, the nocturnal dose is 150mg of ranitidine and 400mg of cimetidine.[30,32,33] Using these above maintenance doses, several clinical studies have demonstrated a significantly lower relapse rate for ranitidine than cimetidine. Relapse rates at 12 months were 15-23% for ranitidine and 37-44% for cimetidine.[34,35] The lower rate of relapse for ranitidine may be due to its prolonged suppression of acid secretion.

Since approximately 70% of IV ranitidine and cimetidine and 30-60% of oral doses are excreted in the urine as unchanged drug,[1,36] dosage adjustment is necessary in patients with severe renal impairment (See Table 3). Both drugs are partially removed by hemodialysis. For maximum efficacy, the dose of either drug should be administered after hemodialysis.[1,3,7] Usually, it is not necessary to reduce the dose of either drug in patients with liver impairment.[3,28]

Table 3
DOSAGE ADJUSTMENT FOR RENAL IMPAIRMENT+

Drug	*Parenteral Therapy*	*Oral Therapy*
Ranitidine	50mg q18 - 24 hrs	150mg qhs
Cimetidine	300mg q12hrs	300mg q12hrs

+ Creatinine clearance less than 50ml/min

Use of Oral Therapy

Due to the tremendous cost savings to both the patient and the hospital, oral therapy is the preferred route of administration (See Table 2). Use of parenteral H2-antagonists should be reserved for patients who cannot take oral medication or in patients where oral therapy is contraindicated (i.e. active GI bleed, conditions which will not allow for proper drug absorption, etc.).[9,37,38] Early conversion to oral therapy is encouraged whenever possible.

Conclusion

Ranitidine is as efficacious as cimetidine for the treatment and maintenance of various ulcers and pathological hypersecretory states. Oral therapy is preferred due to substantial cost savings and ease of administration. Ranitidine offers several advantages over cimetidine therapy including decreased potential for adverse drug reactions and longer duration of action.

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The Treating Physician's View of Informed Consent: Observations Made in a Retrospective Study

GEORGE ROBINSON, M.D.

ABSTRACT–**Tape recordings of 644 informed consent interviews prior to cardiac surgery were reviewed. They were examined for completeness of disclosure, patient responses, comprehension, possible adverse effects, and decisions made by patients during the interview. Disclosure was over 99% complete for all details required relevant to cardiac surgery. Compliance with advice was 100% for acceptance of recommendation. Comprehension of material was considered variable in degree. Adverse psychological effects were absent. The decision to be operated upon was probably not made during the interview. Malpractice litigation for this group was zero. Both the patient and the surgeon benefited from the informed consent interview, but not in the way the law intended.**

This study was undertaken to define the role of informed consent in the decision making process prior to cardiac surgery.

Tape recordings of 644 informed consent interviews made between 1975 and 1980 were reviewed and examined for the following: completeness of disclosure, patient responses, comprehension, possible adverse effects, and decisions made by patients during the interview. All recorded interviews contained an explanation of the nature of the illness, the nature of the proposed surgical procedure, the risks, potential complications, benefits to be anticipated from a successful surgical procedure, and alternatives to surgical intervention.[1] There was an opportunity for the patient to ask questions of the surgeon. Data obtained permitted some statistical analysis, but the nature of the material required that many conclusions be made that are intuitive.

The study group was similar to those encountered by every cardiac surgeon. Nearly all were inpatients with completed invasive and noninvasive studies, awaiting cardiac surgical management. It was our clinical practice to perform invasive studies only on patients who agreed in advance to be operated upon if the results indicated that surgery was advisable. All patients in this study were advised to undergo open heart surgery after being given full informed consent information by the author. This was usually at the first and often the only preoperative visit. Operative consent forms were often signed, and many patients were prepped for surgery before the informed consent interview took place. Compliance with the advice to be operated upon was 100% among these 644 patients. Fifteen patients deferred their decision at the end of the recorded interview for a variety of reasons. Examination of the medical records revealed that all 15 were eventually operated upon.

Review of the tapes revealed that only 75% of the patients wished to hear all of the informed consent information and, therefore, were able to give valid and informed consent to surgery. Twenty-five percent (25%) refused to hear part or all of the information and, therefore, gave valid but uninformed consent to surgery. Of the 25%, 18% declared that they wished to have absolutely no information whatsoever and 7% asked for insignificant information. For those who were given full informed consent, the completeness of disclosure was found to be in excess of 99% for all material facts.

The question arises as to whether or not the patients actually understood the information given them. All patients were asked if they understood, and the overwhelming majority answered affirmatively. Those that did not understand were informed again until understanding was acknowledged. The degree to which patients understood is probably variable, but there is neither statistical data to support this conclusion nor is there a way to measure actual understanding. Comprehension is obviously difficult because of the highly technical nature of cardiac surgery. It appeared, however, that virtually all patients understood enough to acquiesce comfortably to be operated upon.

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There is no apparent correlation between mortality expectancy and consent to surgery. Of the 644, there were 71 patients who were told that they had an anticipated mortality rate between 10% and 50%. There were no refusals in this group. Thus, the anticipation of a high mortality rate is not characterized by refusal of surgery. The actual mortality rate in this high risk group was 8.5% (6/71).

Negative psychological consequences, such as increase in the level of anxiety, panic, inappropriate or self destructive behavior, or behavior prejudicial to survival was not observed. In fact, it was likely that anxiety diminished when patients were given high quality information that increased the confidence with which they approached a surgical operation.

Aside from strictly medical considerations, patients were influenced by family, friends, finances, and the media. Many patients wanted the information, communication, and concern that resulted from a long conversation with the surgeon.

While the relationship between litigation and informed consent is unclear, the responsibility for non-negligent occurrence of adverse results was effectively transferred during "consent" to the patient instead of being assumed by the surgeon. There were no malpractice law suits filed by any of the 644 patients. Thus, the surgeon is a major beneficiary of informed consent, with an unparalled opportunity to reduce his personal liability. This may have resulted from more realistic expectations following informed consent, as well as an appreciation by the patient of the fact that the physician and surgeon cannot control all eventualities. Of some importance is the fact that informed consent with disclosure of all adverse results does not appear to do any harm.

It was nearly impossible to determine in any individual all of the factors involved in the decision making process. The decision to accept surgery appeared to have been made before the informed consent interview probably as a result of prior contact with the media, cardiologists, nurses, and other advisors. The universal acceptance of advice to be operated upon (100%) is difficult to understand, especially when medical advice warned of an anticipated high mortality rate of 10% to 50% in 71 individuals. Complications such as hemorrhage, stroke, infection, myocardial infarction, and other disasters failed to deter patients from surgery.

The patient and the surgeon each benefits from the law of informed consent, but not in the way it was intended. The patient appreciates the concern and communication intrinsic in the process. The surgeon is substantially protected from medical malpractice litigation. The law had intended to encourage patients to make their own decisions, along with their doctors, on how to proceed with medical care once they had acquired sufficient information from an "informed consent" interview. Patients, however, continued to yield this decision making to experts involved in rendering their clinical care.[2]

Thus, the patients did not utilize the information as the law intended for them to do. The decision to undergo surgery seemed to be made at another time and in another place, apart from the informed consent interview, and in many cases was often made for reasons not fully known to the surgeon. The basic reason for accepting medical advice is the expectation of a favorable clinical outcome, and the analysis of 644 tape recordings supports the view that patients are undeterred by the prospect of possible adverse results.

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How a Bill Becomes a Law

SHELLEY A. MARCUS, J.D.

What is a raised committee bill (RCB)? A proposed bill? How is a bill "boxed"? What is a joint favorable report?

These are all terms used to describe the status or type of a bill in the legislative process. I will be reporting to you, on a monthly basis, the progress of proposed legislation affecting the medical profession as well as public health in general.

In order for these reports to be meaningful, it is important to first be familiar with the legislative process and the long road a bill travels before it finally becomes a law.

SESSIONS

The constitution provides for regular sessions in odd-numbered years to commence on the Wednesday following the first Monday in January and to adjourn no later than the Wednesday following the first Monday in June. The upcoming session is in an odd-year and will open on January 7, 1987, and close on June 3, 1987. Even-year sessions begin on the Wednesday following the first Monday in February and adjourn no later than the Wednesday following the first Monday in May.

OVERVIEW

There are certain basic procedures that must be followed before a bill can become a law. All bills will be referred to and reviewed by the committee which has jurisdiction over their subject matter. Quite often bills are reviewed by more than one committee because of concurrent jurisdiction. For example, a bill dealing with Medicare assignment will be referred to the committees on Public Health, Human Services, Insurance and perhaps, Appropriations, if it has a fiscal impact on the State.

All bills must receive a public hearing. These hearings are conducted by Committees in order to afford the people the opportunity to express their views on the proposal. The committee also has a chance to gather data on each bill. This aids the members in making a well-informed decision when they vote on whether to report a measure out of the committee.

Finally, all of the definitions and procedures described below are subject to both the Joint Rules (governing both houses) and the rules of each house. The Joint Rules have a greater impact on the fate of a bill because they govern procedures such as the committee referral process, public hearings, committee deadlines, bill drafting, basic committee procedures, and the transmittal of bills to the Governor for his approval. These rules are adopted at the commencement of every odd-numbered session year and remain in effect for two years. There are generally only minor changes made in the Joint Rules from session to session; therefore my remarks are based on the 1985-1986 Joint Rules.

Each house also adopts its own set of rules. These rules govern the duties of the legislative leaders and the parliamentary practice of each house. They are also adopted on a biennial basis.

PRELIMINARY ACTION

Prior to the opening of the odd-year legislative session and for a limited time after its opening (set by the Joint Rules) individual members and members—elect of the General Assembly may file *proposed bills* and resolutions in the house to which they were elected. In even-year sessions, individual legislators may introduce only those proposed bills that are of a fiscal nature. Standing committees as a whole may introduce bills on any topic in any regular session of the General Assembly.

Proposed bills are usually not filed in full statutory language, but rather state briefly the substance of the bill in informal, nonstatutory language. Although rarely done, a legislator may submit a proposed draft in formal language as a proposed bill. Proposed bills may be jointly sponsored by Senators and Representatives, and legislators may co-sponsor a bill originating in either house by requesting the clerk of the House or Senate to add them to the list of sponsors.

COMMITTEE ACTION

All proposed bills are referred to one of eighteen (18) joint standing committees, depending on their subject matter. The committees are "joint" because their members are composed of legislators from both the House and Senate.

The present joint standing committees are as follows (the number of committees and their jurisdiction may change in 1987 as a result of amendments to the existing Joint Rules): Program Review and Investigations, Insur-

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SHELLEY A. MARCUS, J.D., Director of Government Affairs, Connecticut State Medical Society.

ance and Real Estate; Labor and Public Employees; Environment; Human Services; Public Safety; Public Health; General Law; Energy and Public Utilities; Planning and Development; Legislative Management; Transportation; Banks; Government Administration and Elections; Education; Judiciary; Finance, Revenue and Bonding; Appropriations.

The committee first separates the proposed bills referred to it into subject catagories and after providing members an opportunity to express their views, decides whether these proposals merit a public hearing.

A committee may hold a *subject matter* public hearing on proposed bills without having these bills drafted in formal language. After the hearing the committee decides whether to have these bills fully drafted as *committee bills*. A committee may also, and quite often does, vote to prepare fully drafted bills in formal statutory language based on proposed bills. These are called *committee bills*. Lastly, a committee may also choose to draft a bill in statutory language on a wholly new subject. These bills are called *raised committee bills*.

Notice of the public hearing is published in a legislative publication called the *Bulletin*. Hearings are held to give the public, legislators and state agency officials an opportunity to express their views for or against a bill.

After the public hearing the committee meets to decide upon its action on the bill. The committee has several options: 1) A *joint favorable report* (JF) which indicates that a majority of the committee favors the bill and recommends its passage; 2) a *joint favorable substitute* (JFS) which is a bill that has been amended by the committee and is sent to the House or Senate with a favorable recommendation; 3) a vote to reject or *box* the bill; and 4) a *joint unfavorable report* which indicates that a majority of the committee opposes the bill and recommends its rejection. A committee may also vote a *change of reference* or a *favorable change of reference* to another committee when the other committee has overlapping jurisdiction over the subject matter of the bill.

SENATE AND HOUSE ACTION

The bill must first be received and approved by the Legislative Commissioner's Office (the office which is responsible for drafting all legislation) before being reported to the house in which it was introduced. The bill is then delivered to the clerk of the house of origin. Each favorably reported bill receives a file number and is placed on the Calendar (the publication listing all bills reported out of committee) in the order in which it is received from committee. The bill is then printed (called the *file copy*) for the files of the members of both houses. Copies must be in the members files for two session days and have been printed on the Calendar for three days before they are ready for action. These bills are marked with an "XX" (meaning "double starred") on the Calendar.

When the bill has received an *unfavorable report*, it is only printed once on the calendar. The House or Senate then votes on a motion to reject the bill. If the house of origin overturns the unfavorable report (ie. votes to reject the committee's recommendation), the bill then goes back to the Legislative Commissioner's Office and goes through the same process as a bill originally receiving a favorable report.

A bill to which no objection is expected may be designated by the majority and minority leaders of the house in which it originated to be put on the *Consent Calendar*. These bills are passed on motion without discussion. Upon the objection of a legislator, a bill must be transferred from the Consent Calendar to the regular Calendar. Such removal will *not* result in delay of consideration of the measure.

When a bill on the regular Calendar is called for action, a member of the committee out of which the bill was reported, explains to the members of the House or Senate the committee's reasons for so doing and a general debate on the bill is in order. Members of the house acting on the bill may offer amendments before the final vote. In that event, amendments must be voted on separately and *before* the vote on the bill. A majority of each house constitutes a quorum to do business and a simple majority is needed for passage or failure of a bill.

After a bill has passed the house in which it was introduced, it is held over for one day to provide for the opportunity for a motion to reconsider. If the bill is not reconsidered, it is sent to the other house for placement on its Calendar. It must again be "double-starred" before it is ready for action. If the other house amends the bill differently from the first house, the bill is returned to the house of origin and voted on again for concurrence in the amendments. If the amendments are not in concurrence after this second vote, a Conference Committee may be appointed for the purpose of reaching agreement. If one or both houses reject the Committee's report, the bill fails.

ACTION BY THE GOVERNOR

After a bill has passed both houses, it is transmitted to the Governor for approval or disapproval. If the Governor receives the bill while the legislature is in session, he has five calendar days after receipt, exclusive of Sundays and holidays, within which to sign or veto it. If he does not sign or veto the bill within this period of time, the bill becomes a law. If the bill is vetoed, it is returned to the house of origin for reconsideration and can only become a law if passed by a two-thirds vote of the members of the house.

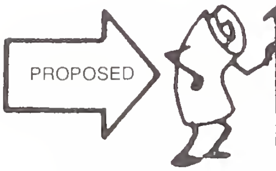
If the Governor receives the bill after the session has adjourned, he has fifteen calendar days after receipt within which to sign or veto the bill. If the Governor signs the bill or takes no action, the bill becomes a law.

If the Governor vetoes any bill or bills after adjournment, the General Assembly is reconvened for the sole purpose of reconsidering and if the Assembly so desires, repassing these bills. Again, a two-thirds vote of the members of each house is required to override a veto.

Public Acts become effective on October 1st following passage, unless otherwise specified in the legislation.

HOW A BILL BECOMES A LAW

1



Introduction in the House

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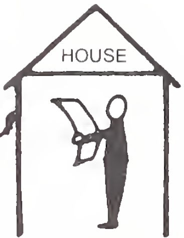

First reading in the House

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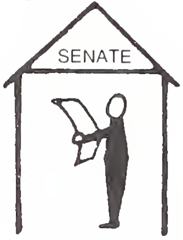

Sent to Senate for first reading

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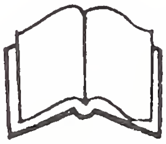

Bill title, number and sponsors printed in the House and Senate Journals

5

Bill sent to one of the joint standing committees of the General Assembly

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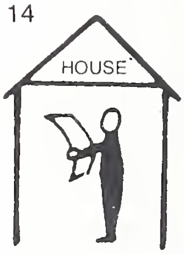

Third reading Debate and amendments

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Vote on bill

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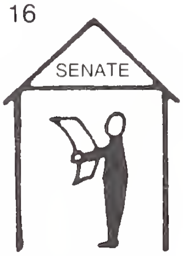
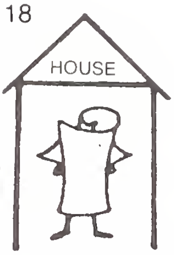


A "yes" vote sends bill to other house for second reading and placement on calendar

17

Other house votes on bill

18



Returned to first house for concurrence if amended by second house; if not amended, sent to the governor

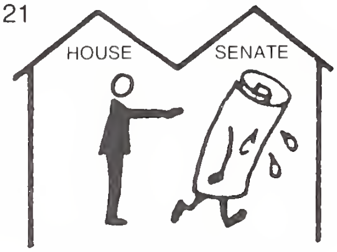
19

If House and Senate cannot agree, bill sent to special joint conference committee

20

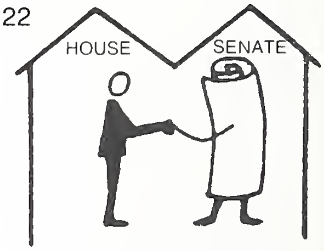
If conference committee reaches agreement, report sent to both houses

21



If one or both houses reject changes, bill fails

22



If both houses pass the bill, it is sent to the governor

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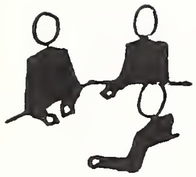


Committee may 1) hold bill as is for public hearing; 2) combine with others and have drafted as a committee bill; 3) take no action ("box"). (Committees may also write new ("raised") committee bills)

7

Committee holds public hearings for public, legislators, state agency representatives on all bills still under consideration

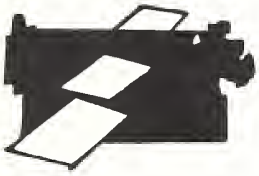
8

Committee acts on bill (reports favorably, unfavorably or "boxes" with no report)

9

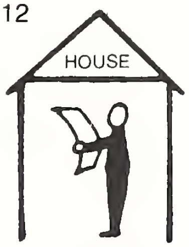
Bills requiring appropriations are referred to Appropriations Committee for approval (Bill can die here)

13



Final printing of bill

12



Second reading
Bill is assigned a calendar number

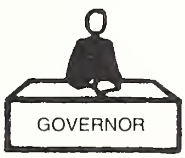
11

Office of Fiscal Analysis adds fiscal note

10

Bill sent to Legislative Commissioners to be checked for accuracy)

23



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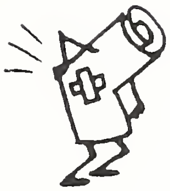

If governor vetoes bill is returned to house in which it originated

25

Bill becomes law if 1) governor signs it, 2) governor fails to sign within 5 days during legislative session or 15 days after adjournment, 3) vetoed bill is repassed in each house by a ⅔ vote of elected membership

The Utility of Therapeutic Plasmapheresis for Neurological Disorders

NATIONAL INSTITUTES OF HEALTH

Therapeutic plasmapheresis, or therapeutic plasma exchange (TPE), is a method for removing toxic elements from the blood. It is performed by removing blood, separating the plasma from the formed elements, and reinfusing the formed elements together with a plasma replacement.

Therapeutic plasma exchange has been used to remove unwanted substances from the blood. These include toxins, metabolic substances, and plasma constituents implicated in disease, such as complement or antibodies. The ability to remove antibody and other immunologically active substances from the blood has led to the use of TPE as a therapy for neurological conditions in which autoimmunity is believed to play a role. It is estimated that half of the 20 000 to 30 000 TPE procedures performed annually at present in the United States are done on patients with neurological disorders.

Reports regarding use of TPE in the medical literature have generated both enthusiasm and controversy. Clinical trials to assess efficacy of TPE have now been completed. In several neurological disorders, conflicting interpretations of their results have occurred.

To resolve these conflicts, the National Institute of Neurological and Communicative Disorders and Stroke, the Clinical Center, and the National Institutes of Health Office of Medical Applications of Research convened a Consensus Development Conference on the Utility of Therapeutic Plasmapheresis for Neurological Disorders from June 2 to 4, 1986. Experts from North America and Europe presented data regarding the risks and benefits of TPE for the treatment of myasthenia gravis (MG), Eaton-Lambert syndrome (ELS), Guillain-Barré syndrome (GBS), chronic inflammatory demyelinating polyneuropathy (CIDP), paraproteinemic neuropathies, amyotrophic lateral sclerosis, and multiple sclerosis (MS). They also discussed alternative therapies. Additionally, experts presented information regarding the appropriate techniques for performing TPE.

The consensus panel considered scientific evidence and addressed the following questions:

1. Is therapeutic plasmapheresis of benefit for neurological diseases? If so, for which diseases and under what circumstances?
2. What are the risks of plasmapheresis?
3. If effective, what are the mechanisms of action?
4. Is efficacy influenced by technique?
5. What is the relationship of plasmapheresis to other therapies?
6. What insights has plasmapheresis provided to suggest relevant clinical or basic research strategies?

1. Is therapeutic plasmapheresis of benefit for neurological diseases? If so, for which diseases and under what circumstances?

Myasthenia Gravis

A considerable body of experimental animal and human clinical data has implicated an antibody-mediated attack on the acetylcholine receptor (AChR) in the pathogenesis of MG. Although the factors that trigger this antibody response are not understood, recent therapy has been directed toward lowering the levels of antibodies against the AChR.

The rationale for the use of TPE in MG is clear. Despite several open, uncontrolled clinical trials suggesting that TPE induces short-term improvement in patients with MG and numerous anecdotal reports of dramatic improvement, a controlled trial of TPE in MG has never been done. Nevertheless, the panel is persuaded that TPE can be useful in strengthening patients with MG before thymectomy and during the postoperative period. It can also be valuable in lessening symptoms during the initiation of immunosuppressive drug therapy and during an acute crisis.

Eaton-Lambert Syndrome

Eaton-Lambert syndrome seems to be an immune-mediated disease of the myoneural junction. It is characterized by weakness that may decrease with exercise and by specific electromyographic abnormalities. The evidence that it is an immune-mediated process comes from its association with other autoimmune diseases, presence of organ-specific autoantibodies, and the fact that

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From the Office of Medical Applications of Research, National Institutes of Health, Bethesda, Md.

Reprint requests to Office of Medical Applications of Research, Bldg 1, Room 216, National Institutes of Health, Bethesda, MD 20205 (Michael J. Bernstein).

the electrophysiological features of the disease can be passively transferred to animals by immunoglobulin. Sixty-five percent of patients have an associated small-cell carcinoma of the lung.

The rationale for the use of TPE in ELS is based on the presence of a serum antibody that blocks the release of neurotransmitter from the presynaptic membrane. Only a limited number of patients with ELS have had TPE. The data at hand, from a single uncontrolled trial, while suggestive, cannot be taken as definitive. Nevertheless, these preliminary data, taken in conjunction with the antibody-mediated pathogenesis of the disease, persuade the panel that TPE may well have a role in the treatment of this syndrome.

Chronic Inflammatory Demyelinating Polyneuropathy

Chronic inflammatory demyelinating polyneuropathy is thought to be an immune-mediated process. It is characterized by a progressive or a relapsing course. Motor and sometimes sensory function are compromised or lost, as are reflexes.

As shown in a randomized, double-blind, sham pheresis trial of severely affected patients, a brief course of TPE may produce benefit, but only for some manifestations of the disease and only transiently. Approximately one third of patients showed benefit in this trial; it was not possible to predict who would respond. Results from uncontrolled trials have been comparable. The role of TPE in patients with mild CIDP has not been explored. There may be a place for repeated courses of TPE in CIDP.

Guillain-Barré Syndrome

Guillain-Barré syndrome is an acute monophasic demyelinating neuropathy characterized by loss of motor strength, loss of reflexes, and variable sensory loss. Therapeutic plasma exchange appears to be of benefit in GBS based on the results of multicenter randomized clinical trials comparing TPE with supportive care. The panel notes that no trial comparing TPE with sham TPE has been done. Benefit has been seen in patients with severe disease and when TPE has been started early in the course of the illness, preferably within two weeks of onset of symptoms. Under these circumstances, TPE may shorten duration of motor weakness sufficiently to reduce hospital stay. For patients able to breathe without ventilatory support at the time of the first plasma exchange, TPE may also reduce the time spent on a respirator if ventilatory assistance is subsequently needed.

Therapeutic plasma exchange is recommended only for GBS patients with, at a minimum, severe weakness at the time of the first plasma exchange. Severe weakness is defined as the ability to walk only with support. It is unclear whether patients able to walk without support will benefit from TPE.

The efficacy of TPE in GBS has been demonstrated using a schedule of 40 to 50 mL/kg per exchange (approximately one plasma volume) for a total of three to five exchanges over seven- to 14-day period. The volume, frequency, and number of exchanges to achieve optimal benefit remain to be established. Because these exchanges involve seriously ill patients (many on respirators), it is recommended that TPE be done in hospitals with personnel experienced in performing this procedure on critically ill patients.

Paraproteinemia

Neuropathy can occur in patients with both malignant and nonmalignant paraproteinemia. The neuropathy seems to be associated with binding of immunoglobulin to peripheral nerve myelin. Most frequently, binding occurs with myelin-associated glycoprotein and with glycolipids. In most patients, the immunoglobulin is IgM. These paraproteinemias make up a clinically and immunologically heterogeneous group of disorders. Whether TPE should play a role in treating these disorders has not been demonstrated by the studies conducted to date.

Amyotrophic Lateral Sclerosis

Amyotrophic lateral sclerosis is characterized by progressive degeneration of motor neurons with consequent weakness, atrophy, and fasciculations. It may be associated with signs of corticobulbar or corticospinal tract involvement. Based on the evidence at hand, the panel concludes that TPE is of no benefit in treating this disorder.

Multiple Sclerosis

The etiology and mechanism of central nervous system myelin breakdown in MS are unknown. There is reason to believe that immune processes play an important role in pathogenesis. The rationale for TPE in MS includes changes in T-cell regulation, immunoglobulin in the cerebrospinal fluid, and a profound lymphocytic infiltrate in the active MS lesion. Other perturbations of the immune response involving both humoral and cell-mediated immunity are less clearly defined but could also provide a rationale for TPE.

There is no established treatment that alters the course of MS. Adrenocorticotropic hormone has been shown to lessen symptoms during acute exacerbations but not to alter the course over the longer term. Most current experimental treatment protocols distinguish among the various expressions of the disease. Thus, trials have been carried out in exacerbating-remitting MS and in progressive MS. A number of controlled trials involving diverse experimental protocols are under way currently, and the state of MS treatment is in flux.

The proper role of TPE in the treatment of MS has not been defined. A controlled study of TPE in acutely exacerbating MS has not been completed. One double-blind, randomized, controlled sham study of TPE in progressive MS has been published. In this trial, prednisone, low-dose cyclophosphamide, and immunoglobulin were given together with TPE, and the TPE was continued once weekly for five months. Benefit was reported, but the study has not been confirmed. Until there is confirmation of the benefit of TPE in progressive MS, the panel feels that TPE in MS should be viewed as an investigative procedure.

2. What are the risks of plasmapheresis?

No systematic data have been collected to quantify the risks of TPE. Fifty fatal reactions associated with TPE between 1978 and 1983 have been reported worldwide. Of these, 16 were cardiac and 14 respiratory. Other deaths resulted from anaphylaxis, pulmonary thromboembolism, vascular perforation, hepatitis, systemic hemorrhage with disseminated intravascular coagulation, and sepsis. It is estimated that there were three deaths per 10 000 procedures. The risk of serious or fatal reactions may be greater when plasma is used as the replacement fluid.

Risk factors that have been identified for all apheresis procedures may be classified as device or procedure related. Device-related risk factors that are potentially major include red blood cell hemolysis, overheating of blood, and inaccurate delivery of anticoagulant and/or replacement fluids.

Procedure risk factors considered to have potential for major complications include the following:

- Citrate-induced hypocalcemia.
- Replacement with fluids depleted of coagulation factors, proteins, or electrolytes.
- Replacement fluids containing plasma. These have the capacity to transmit infection (eg, hepatitis, cytomegalovirus, and human T-cell lymphotropic virus type III).
- Allergic reactions leading to anaphylaxis.
- Hemorrhage secondary to systemic anticoagulants.
- Activation of coagulation, complement, fibrinolytic cascades, and/or aggregation of platelets.
- Fluid imbalance.
- Problems with vascular access.

These potential complications make it necessary to reserve TPE for situations of expected major benefit. Because it is necessary to properly define the number, extent, and frequency of procedures to be performed, the total duration of the treatment, and the factors (eg, laboratory and vital signs) to be monitored and interpreted during the preprocedure and postprocedure period, TPE should only be performed in an apheresis unit experienced with such matters.

3. If effective, what are the mechanisms of action?

In six conditions (MG, ELS, GBS, CIDP, paraproteinemic neuropathy, and MS), patients have been shown to benefit or possibly benefit from TPE. The response or failure to respond to TPE could help clarify disease mechanisms. Several immunopathogenic mechanisms exist for neural tissue injury. To the extent that TPE improves the course of the disorders considered at this conference, specific or nonspecific soluble factors are likely to mediate, be responsible for, or contribute to target organ damage. Criteria to establish that TPE removes one or more specific pathogenic substances are as follows:

1. Therapeutic plasma exchange leads to a demonstrable, even if brief, improvement in function in the treated patients.

2. Plasma removed by TPE ideally produces, on passive transfer, a comparable disease in animals.

3. Purification of one or more of the plasma components removed by TPE and a demonstration that the component(s) is effective in passively transferring the disease identifies the component(s) as a mediator of the disease.

As a control, plasma from patients with the same target tissue damaged by a different mechanism should not produce the effect. This would eliminate the possibility of an epiphenomenon.

Using the three criteria listed above, the diseases considered in this conference can be compared. The response of patients with MG and ELS to TPE has contributed to the understanding of those disease mechanisms. In both diseases, TPE removes a pathogenic antibody. Whether comparable understanding will be generated by TPE studies of patients with GBS, CIDP, paraproteinemic neuropathy, or MS remains to be seen.

Therapeutic plasma exchange also may work by removing nonspecific factors such as mediators of inflammation and lymphokines that contribute to the severity of a process without being its root cause. Optimally, efficacy of TPE should be rigorously tested against a sham TPE control for each disease for which a trial is carried out.

4. Is efficacy influenced by technique?

Therapeutic plasma exchange offers the capability of removing molecules of different molecular weights that have accumulated in the intravascular space. It is not known to have any effect on ablating primary pathological processes. For TPE to be accepted as an effective therapy, relationships must be established between removal of some pathological factor and reversal of morbidity or mortality. Under ideal circumstances, this implies that the molecular constituents of the pathological factor(s) are known; their intravascular and extravascular distributions are known; and something is known of their rates of synthesis, kinetics of diffusion across the capillary membrane, and the minimal quantity that must be removed to produce an observable response.

There appeared to be reasonable standardization of steroid and immunosuppressive drug regimens in protocols reviewed by the panel. There was great variability, however, among the TPE protocols relative to (1) the volume processed per exchange, (2) the frequency with which the procedure was performed, (3) the total number of procedures performed, and (4) the duration of the total TPE treatment. How much this variability contributed to the outcome of the studies, either positively or negatively, is not clear. Standardization of TPE regimens within trials is desirable and is recommended, with consideration given to calculated patient plasma volume.

In addition to the physiological and scientific issues related to the patient, each TPE device has its own individual geometry that influences plasma separation efficiency. Both this device variable and the expertise of the apheresis device operator introduce technique variables that could alter the efficacy of the treatment. Another dynamic factor that may contribute to the efficacy of TPE is the extent of binding of the pathogenic factor to the target tissue.

5. What is the relationship of plasmapheresis to other therapies?

Myasthenia Gravis

Treatment modalities in MG have included anticholinesterases, thymectomy, corticosteroids, adrenocorticotropic hormone, ISDT, and TPE. Most clinicians currently agree that the mainstay of therapy (particularly in younger patients) is thymectomy. This is sometimes coupled with the administration of corticosteroids and (in severely affected refractory patients) ISDT. Therapeutic plasma exchange appears to be useful in patients with chronic MG who either do not respond to or have deleterious side effects from corticosteroids or ISDT. It is also useful in patients who demonstrate acute deterioration either because of the disease process itself or the steroid therapy. Therapeutic plasma exchange also appears to be helpful in preparing patients for thymectomy. The duration of clinical improvement induced by a course of TPE in MG patients is generally of the order of four to six weeks.

Eaton-Lambert Syndrome

The treatment of ELS has consisted of corticosteroids and ISDT. Short-term improvement in muscular weakness can be effected by TPE. This is particularly useful in those patients with small-cell carcinoma of the lung. It also is useful when ISDT is not indicated. Long-term clinical improvement seems to be sustained better, however, by corticosteroids and ISDT than by TPE. No information is available about the use of TPE by itself without concomitant corticosteroids.

Guillain-Barré Syndrome

The treatment of GBS in the past has been supportive only. No clear benefits have been demonstrated so far with corticosteroids or ISDT. Current studies of the role of TPE in GBS suggest that TPE is effective when used early in the disease for severely affected individuals. Concurrent use of corticosteroids has not been shown to have any additional demonstrable beneficial effect.

Chronic Inflammatory Demyelinating Polyneuropathy

Therapeutic plasma exchange may be useful in patients with CIDP, particularly those who have failed to respond to corticosteroids and ISDT. Repeated courses of TPE may be required to sustain benefits. Whether long-term ISDT should be given in conjuction with repeated courses of TPE remains unknown.

Multiple Sclerosis

In the only controlled trial of TPE in MS, TPE was used in conjunction with corticosteroids, ISDT, and immunoglobulin. There is no information available about the use of TPE alone in MS patients from controlled trials.

6. What insights has plasmapheresis provided to suggest relevant clinical or basic research strategies?

Myasthenia Gravis

The discovery that antibodies directed against the AchR are present in MG preceded experimental trials of TPE in this disease. Trials of TPE in MG flowed naturally from this discovery. On the other hand, a putative beneficial effect of TPE in ELS preceded the demonstration of antibodies directed against the terminal axon in this disease. Similarly, in patients with a myasthenialike clinical presentation but no antibodies to the AchR, a successful trial of TPE spurred a search for disease-relevant antibodies and ultimately their discovery. From these observations, the following conclusions can be drawn: (1) When an antibody is found in a disease of unknown cause that *could* be relevant to its pathogenesis, a circumscribed trial of TPE may provide supporting evidence, albeit indirect, that the antibody in question is disease related, and (2) trials of TPE may be worthwhile in certain neurological diseases of unknown cause because they may provide clues to pathogenesis. Criteria for selecting a disease for study might include fluctuations (indicating a potential for recovery) and available outcome measures that are simple, sensitive, and readily quantified.

Removal of antibody may not provide a total explanation for effects seen following TPE. Thus, even in MG, where anti-AChR antibody is held to cause the disease, disease severity may be influenced by other circulating factors at present unknown. Antibody presence correlates with MG, but antibody levels do not reflect disease severity or predict response to TPE.

Guillain-Barré Syndrome

The apparent efficacy of plasmapheresis in GBS leads to several questions:

1. What is the optimum TPE regimen in GBS? There is a suggestion that even one or two treatments can sometimes abort progression. This point requires clarification.

2. Should mildly affected GBS patients be treated? A controlled trial is needed.

3. Which patients should *not* be treated? Are those who already require respirator assistance or in whom illness has been present for more than two weeks less likely to benefit from TPE?

4. What is the mechanism of action of TPE?

Removal of antibody alone may not explain the beneficial effect of plasmapheresis in GBS. Circulating lymphokines and circulating acute-phase reactants (common after infectious illness) may contribute to disease progression, and their removal may have beneficial effects. It would be of interest to follow levels of these factors as well as antimyelin antibodies and relate them to the clinical response.

Guillain-Barré syndrome following infection with *Campylobacter jejuni* may be more severe than GBS following other infections and perhaps less responsive to TPE. It will be important to develop data that predict patient response to TPE.

Multiple Sclerosis

Further studies are needed to clarify whether treatment with TPE benefits patients with MS.

Other Considerations

The possibility that sham pheresis is not merely a placebo should be tested. Optimal regimens have not been established for any neurological condition in which TPE has a role in management.

Conclusion

Therapeutic plasma exchange is a promising new mode of therapy for a limited number of neurological diseases. Its effect, when seen, is relatively short lived. This need not be a problem in monophasic diseases of short duration such as GBS but poses limitations in the management of chronic disease. In chronic diseases, its use should, in general, be viewed as a short-term expedient rather than as a definitive treatment. Therapeutic plasma exchange has offered new insights into neurological disease pathogenesis and can be expected to continue to do so.

Members of the Concensus Development Panel were Barry G. Arnason, MD, Professor and Chairman, Department of Neurology, University of Chicago; Judith Areen, JD, Professor of Law, Associate Dean, Georgetown University Law Center, Professor of Community and Family Medicine, Georgetown Medical Center, Washington, DC; Robert J. Baumann, MD, Associate Professor of Neurology, Head, Child Neurology Program, Department of Neurology, University of Kentucky, Lexington; S. Mitchell Freedman, MD, Raleigh Neurology Clinic, Raleigh, NC; Judith D. Goldberg, AB, SM, ScD, Department Head, Statistical Design and Analysis, Medical Research Division, American Cyanamid Company, Lederle Laboratories, Pearl River, NY; VADM Thor Hanson, USN. (Retired) President and CEO, National Multiple Sclerosis Society, New York; Jeane P. Hester, MD, Professor of Medicine, Chief, Pheresis Service, University of Texas System Cancer Center, Houston; Nelson G. Richards, MD, Clinical Professor of Neurology, Medical College of Virginia, Virginia Commonwealth University, Attending Neurologist, McGuire Veterans Hospital, Richmond, Va; Paul J. Schmidt, MD, Director, Southwest Florida Blood Bank, Inc, Professor of Pathology, University of South Florida College of Medicine, Tampa; Donald H. Silberberg, MD, Professor and Chairman, Department of Neurology, University of Pennsylvania School of Medicine, Hospital of the University of Pennsylvania, Philadelphia; Parker A. Small, Jr, MD, Professor of Immunology, Professor of Pediatrics, University of Florida College of Medicine, Gainesville; Leslie P. Weiner, MD, Chairman, Department of Neurology, University of Southern California, Los Angeles; John N. Whitaker, MD Professor and Chairman, Department of Neurology, University Station, University of Alabama at Birmingham.

Members of the Planning Committee were Barry Arnason, MD, Professor and Chairman, Department of Neurology, University of Chicago; Marinos Dalakas, MD, Senior Investigator, Office of the Clinical Director, National Institute of Neurological and Communicative Disorders and Stroke, National Institutes of Health, Bethesda Md; Mark Hallett, MD, Clinical Director, National Institute of Neurological and Communicative Disorders and Stroke, National Institutes of Health, Bethesda, Md; Harvey G. Klein, MD, Chief, Department of Transfusion Medicine, Clinical Center, National Institutes of Health, Bethesda, Md; Henry F. McFarland, MD, Deputy Chief, Neuroimmunology Branch, National Institute of Neurological and Communicative Disorders and Stroke, Intramural Research Program, National Institutes of Health, Bethesda, Md; Dale E. McFarlin, MD, Chief, Neuroimmunology Branch, Intramural Research Programs, National Institute of Neurological and Communicative Disorders and Stroke, National Institutes of Health, Bethesda, Md; Alvaro Pineda, MD, Director, Apheresis Laboratory, Mayo Clinic Blood Bank and Transfusion Service, Rochester, Minn; William H. Pitlick, PhD, Deputy Director, Convulsive Development and Neuromuscular Disorders Program, National Institute of Neurological and Communicative Disorders and Stroke, National Institutes of Health, Bethesda, Md; Martin Rose, MD, JD, Chief Medical Officer, Office of Medical Applications of Research, National Institutes of Health, Bethesda, Md; Allen D. Roses, MD, Professor and Chief, Division of Neurology, Director, Duke Neuromuscular Research Clinic, Duke University Medical Center, Durham, NC; Zekin A. Shakhashiri, Msc, MD, MPH, Senior Medical Advisor, Legislation Analysis Branch, Administration and Analysis, Office of the Director, National Institute of Neurological and Communicative Disorders and Stroke, National Institutes of Health, Bethesda, Md; Emanuel M. Stadlan, MD, Deputy Director, Demyelinating, Atrophic, and Dementing Disorders Program, National Institute of Neurological and Communicative Disorders and Stroke, National Institutes of Health, Bethesda, Md; Richard S.A. Tindall, MD, Associate Professor of Neurology, Director, Neuromuscular Treatment Center, Southwestern Medical School, Dallas; Michael J. Bernstein, Director of Communications, Office of Medical Applications of Research, National Institutes of Health, Bethesda, Md; Sylvia Schaffer, Chief, Office of Scientific and Health Report, National Institute of Neurological and Communicative Disorders and Stroke, National Institutes of Health, Bethesda, Md.

The conference was sponsored by the National Institute of Neurological and Communicative Disorders and Stroke, Murray Goldstein, DO, MPH, Director; Clinical Center, National Institutes of Health, John L. Decker, MD, Director, Office of Medical Applications of Research, Itzhak Jacoby, PhD, Acting Director.

CSMS-IPA, Inc.: Procedure for Active Membership

(Admission and Revocation)

CSMS IPA-HMO STEERING COMMITTEE

A. Criteria for Active Membership

In order to be admitted to active membership and to thereafter retain active membership in the CSMS Individual Practice Association (hereinafter "IPA"), you must meet the following requirements as determined by the IPA Board of Directors:

1. Be of good standing in the medical community including holding a current unrestricted license to practice medicine recognized by the appropriate licensing authority of the State of Connecticut.
2. Not have been convicted of a felony or a crime involving moral turpitude, dishonesty, or false statement, or other acts which may be grounds for suspension, or termination of your right to practice.
3. Have staff privileges on the staff of a hospital which has contracted with the M.D. HMO, Inc. (hereinafter the "HMO") unless exempted by the Board of Directors.
4. Be able to assure that services are available on a twenty-four hour a day, seven days a week basis, as required by the IPA-HMO Service Agreement.
5. Have sufficient facilities and support staff to enable you to provide all the services which may be required pursuant to the Physician's Agreement with IPA.
6. Have adequate medical malpractice insurance as required by the IPA-HMO Service Agreement.
7. Be willing to enter into and abide by the IPA-Physician Agreements.
8. Conduct yourself with professional demeanor and be of good moral character and integrity. (A finding, by the Board of Directors, that a physician has engaged in gross misconduct, whether as a physician or a citizen, shall indicate that this requirement is not satisfied. Such a finding shall be made only after the Board of Directors has made a reasonable effort to obtain the relevant facts and makes such finding in the reasonable belief that it is warranted by the facts.
9. Be a member in good standing of your county medical association and the Connecticut State Medical Society, or have an active application pending before such association.

B. Procedure for Admission

1. The responsibility for IPA membership procedures and review lie with the Membership/Credentials Committee (the "Committee"). All applications for active membership will be referred to the Committee which shall undertake an examination to determine if the applicant meets all the criteria for active membership stated hereinabove in Section A.
2. If the Committee determines that the applicant meets the criteria for active membership, it shall so notify the Board of Directors. The Board will then approve the application unless it receives further information indicating that the criteria have not been met. If the Board receives such information, it will return the application to the Committee for further examination.

C. Denial of Membership

1. If the Committee determines that the applicant has failed to meet the criteria for active membership, it will so notify the Board of Directors and will give notice to the applicant that it intends to reject the application. Such notice shall include reasons for such rejection and afford the applicant an opportunity to be heard and to present additional information to the Committee with respect to such application. The applicant shall have thirty (30) days from the date the notice is received to respond with additional information and/or petition the Committee for a hearing on the matter. Any failure to petition the Committee within said thirty (30) days shall constitute a waiver of the applicant's right to such a hearing. If a timely request for a hearing is made by the applicant, the Committee shall convene a hearing within thirty (30) days of the Committee's receipt of such a request.
2. The hearing shall be informal and non-adversarial. The applicant may present material which the Committee deems relevant to the applicant's application for active IPA membership. The Committee may present the information upon which it based its decision. After all the relevant information is presented to the Committee, the Committee may adjourn the hearing to consider the issue of whether the appli-

cant shall be admitted. If the Committee decides that the applicant does not meet the active membership criteria, it shall so notify the applicant, in writing, of its decision and the reasons therefor.

D. Intermediate Sanctions

1. Upon referral from the Board of Directors, QAURRM Committee of Medical Director, the Committee shall notify the member of alleged violation of membership criteria. If applicable to the issue in question, a physician must be given a full and fair opportunity to correct the alleged violation within a forty-five (45) day period.
2. If the physician fails to correct such violation, the Committee shall consider whether intermediate measures may be applicable in each case and if so, propose such remedial measures, which may include but not be limited to temporary suspension, probation, non-payment, repayment, clinical supervision, audit, educational requirements, limitation of credentials and reprimand.

E. Revocation of Active Membership

1. A physician's active membership may be revoked for violation of any of the criteria for active membership of breach of the IPA Physician Agreement. At any time, a physician may be immediately suspended from active membership upon a determination by the Board that said suspension is in the plan subscribers' best interest.
2. If the Committee determines that the member has violated the criteria for active membership, it will so notify the Board of Directors. After receipt of such notification, the Board will give notice to such member that it is considering revocation of his or her active membership. Such notice shall include the reasons for such revocation and afford the member an opportunity to be heard and to present additional information to the Board with respect to such revocation. The member shall have thirty (30) days from the date the notice is received to respond with additional information and/or petition the Board for a hearing on the matter. Any failure to petition the Board within thirty (30) days shall constitute a waiver of the member's right to such a hearing. If a timely request for a hearing is made by the member, the Board shall convene a hearing within thirty (30) days of the Board's receipt of such a request.
3. The hearing shall be informal and non-adversarial. The member may present material which the Board of Directors deems relevant. The Committee may present the Board with the information upon which the Committee based its decision. After all the relevant information has been presented to the Board, the board may adjourn the hearing to consider the issue of whether the member's active membership shall be revoked. The Board shall notify the member, in writing, of its decision and the reasons therefor, within thirty (30) days.
4. If the member does not petition the Board for a hearing within the time allowed for such petition, the Board will meet as soon as practicable to evaluate the Committee's determination and any other relevant information. The Board shall notify the member, in writing, of its decision and the reasons therefor, within thirty (30) days.

F. Procedural Standards

1. Decisions made by either the Committee or the Board under Sections C.2, E.3 and E.4 shall be final.
2. All notices related to denial of active membership or revocation shall be sent to the member by first class certified mail, return receipt requested.

Recent Opinions of the Council on Ethical and Judicial Affairs

AMA COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The Council on Ethical and Judicial Affairs has given careful consideration to the following opinions and submits them to the House of Delegates for its information. Ethical pronouncements of the Council on Ethical and Judicial Affairs should not be interpreted, construed, or applied to encourage conduct that violates the law.

Referral of Patients—Disclosure of Limitations

When a physician agrees to provide treatment, he thereby enters into a contractual relationship and assumes an ethical obligation to treat the patient to the best of his ability. Preferred provider organization (PPO) and health maintenance organization (HMO) contracts generally restrict the participating physician's scope of referral to medical specialists, diagnostic laboratories, and hospitals that have contractual arrangements with the PPO or HMO. Some plans also restrict the circumstances under which referrals may be made to contracting medical specialists. If the PPO or HMO does not permit referral to a noncontracting medical specialist or to a diagnostic or treatment facility when the physician believes that the patient's condition requires such services, the physician should so inform the patient so that the patient may decide whether to accept the outside referral at his own expense or confine himself to services available within the PPO or HMO. In determining whether treatment or diagnosis requries referral to outside specialty services, the physician should be guided by standards of good medical practice.

Economic Incentives and Levels of Care

The primary obligation of the hospital medical staff is to safeguard the quality of care provided within the institution. The medical staff has the responsibility to perform essential functions on behalf of the hospital in accordance with licensing laws and accreditation requirements. Treatment or hospitalization that is willfully excessive or inadequate constitutes unethical practice. The organized medical staff has an obligation to avoid wasteful practices and unnecessary treatment that may cause the hospital needless expense. In a situation where the economic interests of the hospital are in conflict with patient welfare, patient welfare takes priority.

Medical Testimony

As a citizen and as a professional with special training and experience, the physician has an ethical obligation to assist in the administration of justice. If a patient who has a legal claim requests his physician's assistance, the physician should furnish medical evidence, with the patient's consent, to secure the patient's legal rights.

The medical witness must not become an advocate or a partisan in the legal proceeding. The medical witness should be adequately prepared and should testify honestly and truthfully. The attorney for the party who calls the physician as a witness should be informed of all favorable and unfavorable information developed by the physician's evaluation of the case. It is unethical for a physician to accept compensation that is contingent upon the outcome of litigation.

From the Council on Ethical and Judicial Affairs, American Medical Association, Chicago.

Report C of the Council on Ethical and Judicial Affairs, adopted by the House of Delegates of the American Medical Association at the Annual Meeting, June 1986.

Members of the Council on Ethical and Judicial Affairs include the following: Nancy W. Dickey, MD, Chairman; John H. Burkhart, MD, Vice-Chairman; W. Scott Chisholm, MD; Charles H. Epps, Jr, MD; Leon M. Henikoff, Jr, MD; David I. Olch, MD; and Russel H. Patterson, Jr, MD.

Quality of Care

AMA COUNCIL ON MEDICAL SERVICE

As government, business, and other payers search for methods to reduce their health care costs, and as competition intensifies in the health sector, efforts to preserve the quality of health care will become increasingly important. Pressure will grow for changes in delivery and financing systems that may tend to reduce the quality of care provided. Public debate will increasingly focus on how to define and measure quality, as health professionals, payers, and consumers address such issues as ensuring quality of care in contracting with provider groups; deceptiveness of advertisements stating that certain providers give "the highest quality health care available"; the feasibility of incorporating a measure of quality in reimbursing hospitals or any other health care providers; and evaluating the effectiveness of various treatment modalities and delivery systems.

The Council believes that the challenge posed by this evolving health care environment is threefold: to foster a broader public understanding of what is meant by the term "high-quality medical care" and of the current mechanisms used to assess and ensure quality; to develop guidelines regarding appropriate methods for assessing or measuring the quality of care; and to encourage wide and systematic use of quality assessment findings to improve the care delivered, and thus increase overall access to care of high quality.

The present report is intended to inform the House of Delegates of the activity undertaken by the Council on Medical Service in response to this challenge and to enlist the House's support in that effort.

Definition of Care of High Quality

At the 1984 Annual Meeting, the House of Delegates adopted Council on Medical Service Report I, which conceptually defined care of high quality as care "which consistently contributes to improvement or maintenance of the quality and/or duration of life." This definition essentially characterizes such care as that which is consistently related to favorable patient outcomes. It recognizes that, *when other variables that could affect outcome (eg, patient age, sex, living environment, attitude toward illness, health history, severity of illness, natural history of the disease, etc) are adequately measured and accounted for,* patient outcome reflects the degree of effectiveness with which health professionals combine their own skill and compassion with the use of technology for the patient's benefit. Implicit in the definition is the need to develop more precise and meaningful criteria of "favorable" outcomes.

The Council believes there are a number of important elements in addition to favorable outcome that can be used to identify care of high quality. All have an important relationship to successful patient outcomes, but can be evaluated independently of such outcomes. Including favorable outcome as one characteristic, therefore, the Council believes that care of high quality should *(a)* produce the optimal improvement in the patient's physiological status, physical function, emotional and intellectual performance, and comfort at the earliest time possible consistent with the best interests of the patient; *(b)* emphasize the promotion of health, the prevention of disease or disability, and the early detection and treatment of such conditions; *(c)* be provided in a timely manner, without either undue delay in initiation of care, inappropriate curtailment or discontinuity, or unnecessary prolongation of such care; *(d)* seek to achieve the informed cooperation and participation of the patient in the care process and in decisions concerning that process; *(e)* be based on accepted principles of medical science and the proficient use of appropriate technological and professional resources; *(f)* be provided with sensitivity to the stress and anxiety that illness can generate and with concern for the patient's overall welfare; *(g)* make efficient use of the technology and other health system resources needed to achieve the desired treatment goal; and *(h)* be sufficiently documented in the patient's medical record to enable continuity of care and peer evaluation.

The Council believes that these eight "essential elements of quality" provide a logical framework around which to organize professionally conducted quality assessment programs and on which to construct specific criteria for such

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From the Council on Medical Service, American Medical Association, Chicago.

Report A of the Council on Medical Service, adopted by the House of Delegates of the American Medical Association at the Annual Meeting, June 18, 1986.

Reprint requests to Council on Medical Service, American Medical Association, 535 N Dearborn St, Chicago, IL 60610 (Nicholas Griffin).

assessment. In addition, a number of these elements can provide patients with a better frame of reference to make judgments about the quality of care that they receive.

Recommendation

The Council on Medical Service recommends that the Association endorse these elements as essential characteristics defining medical care of high quality and that this definition be communicated by the Association to the profession, the payers, and the public through all appropriate channels.

To further enhance public understanding of the complex factors influencing quality of care and facilitate informed choice, the Council has prepared a brochure for distribution through physicians' offices and other channels. It describes the major approaches utilized by medicine to assure care of high quality, ranging from licensure, certification, and accreditation through continuing education and peer review. The Council is now exploring preparation of a second brochure providing specific suggestions as to how patients can evaluate the quality of care they receive.

Guidelines for Quality Assessment

The heart of the program to assess the quality of medical care is peer review, or the evaluation by practicing physicians of the quality and efficiency of services ordered or performed by other practicing physicians. At the 1981 Interim Meeting, the Council proposed and the House adopted nine Principles for Voluntary Medical Peer Review (Council on Medical Service Report A, December 1981). These principles were intended to be generic, and should be found in any organization or system concerned with assessing the quality of medical care.

To supplement these 1981 Principles and further assist in the development of effective peer review programs, the Council has prepared the following guidelines as to the scope and process of quality assessment activity. These guidelines are based on the Council's continuing study of this subject and its discussions with other groups and individuals concerned with improving the quality assessment process. The Council believes that they should be incorporated into any peer review system, whether voluntary or government-mandated, whether sponsored or conducted by medical societies, medical groups, hospital medical staffs, payers, foundations, corporate review programs, or federal agencies. These guidelines help to delineate the "how" of any quality measurement process; the essential elements identified earlier in this report constitute the "what," or the characteristics to be measured. The guidelines are as follows:

1. *The criteria utilized to assess the degree to which medical care exhibits the essential elements of quality should be developed and concurred in by the professionals whose performance will be reviewed.* Such participation is imperative not only to the acceptability of the assessment process, but to assure the relevance of the criteria developed.

2. *Such criteria can be derived from any one of the three basic variables of care: structure, process or outcome. However, emphasis in the review process should be on statistically verifying, linkages between specific elements of structure and process, and favorable outcomes, rather than on isolated examination of each variable.* "Structure" is generally defined as the facilities, equipment, services, and manpower available for care and the credentials and qualifications of the health professionals involved. "Process' refers to the content of care, ie, how the patient was moved into, through, and out of the health care system and the services that were provided during the care episode. "Outcome" refers to the results of care, and can encompass biologic changes in disease, comfort, ability for self-care, physical function and mobility, emotional and intellectual performance, patient satisfaction and self-perception of health, health knowledge and compliance with medical care, and viability of family, job, and social role functioning. While all three care elements have individual merit as indicators of quality, the review system should also attempt to statistically identify and "validate" on an ongoing basis those elements of structure and process that are consistently associated with favorable patient outcomes. This enables more informed attempts to change physician practice behavior when indicated, as well as assuring the relevance of the structure- and process-based criteria used in assessment.

3. *To better isolate the effects of structure and process on outcome, outcome studies should be conducted on a prospective as well as retrospective basis to the degree possible.* It can be difficult to distinguish between the effects of care provided and other factors that can also influence outcome, such as patient age, history and lifestyle, stage of disease, and attitude toward illness. As opposed to after-the-fact outcome evaluation, the identification of "expected" outcomes on a preservice basis, and subsequent comparison with actual results, can allow better identification of individual risk factors and the allocation of patients to similar risk categories better suited to analysis.

4. *The evaluation of "intermediate" rather than "final" outcomes is an acceptable technique in quality assessment.* As a practical matter, it is often more feasible to use intermediate outcomes or immediate treatment results as indicators of quality rather than long-term morbidity and mortality data. In addition, the direct effects of care received are progressively obscured over time.

5. *Blanket review of all medical care provided is neither practical nor needed to assure high quality of care. Review can be conducted on a targeted basis (eg, specific diagnoses, services, or providers), a sampling basis, or a combination of both, depending on the goals of the review process.* The review system may isolate specific aspects of medical care for analysis, such as services exhibiting high variation in regional utilization rates or a high utilization rate generally, diagnoses associated with high mortality or morbidity or for which multiple treat-

ment options exist, or even specific practitioners or institutions. However, judgments as to performance of specific practitioners should be based on assessment of overall practice patterns, rather than solely on examination of single or isolated cases, because of the inherent variability of biologic systems. By contrast, when general assessment of the quality of care provided by a given health care system or across systems is desired, random sampling of all care episodes may be the more appropriate approach.

6. *Both explicit and implicit criteria are useful in assessing the quality of care.* Explicit criteria are highly structured, specific, and written—eg, "specific laboratory/diagnostic tests indicated in treatment of chronic urinary tract infection"—and require little or no individual judgment by the evaluator. Implicit criteria tend to have little or no formal or written structure and tend to be based more on the internalized expectations and judgment of an expert practitioner acting as an evaluator. Explicit criteria are needed to maintain consistency and objectivity in the assessment process; implicit criteria are needed to accommodate legitimate professional differences regarding optimal treatment and allow the unique features of each individual case to be considered.

7. *Prior consultation as appropriate, concurrent peer review, and retrospective peer review are all valid aspects of quality assessment.* Professional consultations when appropriate before a course of treatment is initiated can help assure a medical consensus as to the appropriate course of care and contribute to improved quality. However, the Council shares the strong conviction of this House that the increasing number of payer-instituted, cost-driven programs calling for prior review of the necessity for surgical, medical, or hospital care should not be implemented in a way that would impair the quality of care provided. Two other Council reports before the House at this meeting—Report B and Report D—contain recommendations designed to ensure payer accountability for any prior authorization decisions that may adversely affect the patient and to improve the administration of prior authorization programs contributing to improved quality of care. Similarly, concurrent and retrospective review, when conducted on the same basis, can also make special contributions to the quality assessment process, through "on-line" identification and correction of care deficiencies in the former instance, and increased emphasis on patient outcomes in the latter.

8. *Any quality assessment program should be linked with a quality assurance system whereby assessment results are used to improve performance.* The purpose of quality assessment is to improve the care of patients. Accordingly, the results of such assessment should be systematically conveyed to the practitioners reviewed, and such professionals should be assisted in improving their knowledge and in modifying their practice behaviors where indicated.

9. *The quality assessment process itself should be subject to continued evaluation and modification as needed.* The criteria by which quality of care is assessed, and the quality assessment methodology itself, must be continuously reviewed and revised by the physicians using them to reflect increased scientific knowledge, improved technologies, availability of resources, and other developments relating to the demand for and provision of medical care.

Recommendation

The Council on Medical Service recommends that the Association endorse these guidelines for quality assessment and encourage their incorporation into and use in any system designed to review the quality of medical care.

The Council will continue its study of quality assessment programs and will bring additional recommendations concerning the operation of such programs to the House of Delegates as appropriate. The Council also plans to evaluate the effectiveness of various approaches to quality *assurance*, or the use of assessment findings to improve the care delivered, with the goal of increasing overall access to care of high quality. To assure their equity and validity, all such quality assurance systems must be sensitive to the multiple differences between patients with ostensibly the "same" condition, and should be based on evaluation of overall practice patterns rather than on adherence to specified criteria in single cases. The Council will report its findings to the House in this area as well.

Members of the Council on Medical Service are as follows: Daniel K. Billmeyer, MD, Oregon City; Robert D. Burnett, MD, Los Altos, Calif; George E. Collentine, MD, Milwaukee; Donald K. Crandall, MD, Muskegon, Mich; Roy R. Deffebach, MD, Redwood City, Calif; John A. Finkbeiner, MD, New York; Ronald E. Henderson, MD, Birmingham, Ala; Perry A. Lambird, MD, Oklahoma City; Al J. Osbahr, MD, Glenville, WVa; Mario E. Ramirez, MD, Rio Grande City, Tex; Grant V. Rodkey, MD, Boston; Michael T. Valley, Nashville, Tenn.

Digoxin Antibody Fragments for Digitalis Toxicity

THE MEDICAL LETTER

Digoxin-immune Fab (*Digibind*—Burroughs Wellcome), a preparation of digoxin-specific antibody fragments obtained from immunized sheep, is now available for treatment of life-threatening digoxin and digitoxin overdosage.

PHARMACOKINETICS—Free serum digoxin or digitoxin concentrations drop to unmeasurable levels (less than 0.2 ng/ml) less than one minute after IV injection of Fab. Favorable changes in cardiac rhythm or serum potassium concentration occur within 15 to 30 minutes. The antibody fragments and bound drug are excreted mainly by the kidneys, with an elimination half-life of about 15 to 20 hours in patients with normal renal function. Excretion may be slower in patients with renal impairment.

CLINICAL STUDIES—Digoxin-immune Fab has been used to treat about 150 adults and children with life-threatening cardiac arrhythmias and/or hyperkalemia due to digoxin or digitoxin toxicity that had failed to respond to conventional therapy, including atropine, lidocaine (*Xylocaine*; and others), and phenytoin (*Dilantin*; and others). In most patients, signs of toxicity disappeared within a few hours; the deaths that occurred were attributed mainly to inadequate amounts of antibody fragments available or irreversible heart failure (TW Smith et al, N Engl J Med, 307:1357, 1982; TL Wenger et al, J Am Coll Cardiol, 5:118A, 1985; A Smolarz et al, Clin Toxicol, 23:327, 1985).

INDICATIONS—Since clinical use has been limited and the effects of repeated exposure are unknown, digoxin-immune Fab is not indicated for mild digitalis toxicity. It is recommended for patients in shock or cardiac arrest, or with ventricular arrhythmias such as ventricular tachycardia or fibrillation, progressive bradyarrhythmias such as severe sinus bradycardia, or second- or third-degree atrioventricular block not responsive to atropine. In previously healthy adults, ingestion of more than 10 mg of digoxin (or 4 mg in children), or steady-state serum digoxin concentrations above 10 ng/ml, have been associated with cardiac arrest. Hyperkalemia (over 5 to 6 mEq/l) due to digitalis intoxication may also be an indication for use of the antibody fragments.

ADVERSE EFFECTS—The only adverse effects have been mild increases in congestive heart failure or in the ventricular rate in patients with atrial fibrillation, because of withdrawal of the therapeutic effect of digitalis. Rapid reversal of hyperkalemia may lead to hypokalemia if potassium stores are low. The antibody fragments lack most antigenic determinants, and no hypersensitivity reactions have occurred.

The presence of digoxin-immune Fab in the serum interferes with measurement of serum digoxin concentrations by immunoassay (I Gibb et al, Br J Clin Pharmacol, 16:445, 1983).

DOSAGE AND AVAILABILITY—Digoxin-immune Fab is given intravenously over 30 minutes, or as a bolus if cardiac arrest is imminent; some patients may need a second dose several hours later. It is sold in 40-mg vials, each of which will bind and neutralize about 0.6 mg of digoxin or digitoxin; the average amount used in clinical trials was 10 vials. The manufacturer suggests using 20 vials (800 mg) to treat an acute overdose if the amount ingested is unknown. The supply of the drug is currently limited; it is available in selected medical centers or by phoning the manufacturer at 1-800-334-4828 or (in North Carolina) 1-800-672-7223. The cost of each 4-ml vial is about $175, according to *Drug Topics Red Book*, 1986.

CONCLUSION—Digoxin-immune Fab can be effective for treatment of digoxin or digitoxin overdosage. Since clinical experience is limited and the effects of repeated administration are unknown, it should be reserved for life-threatening digitalis intoxication.

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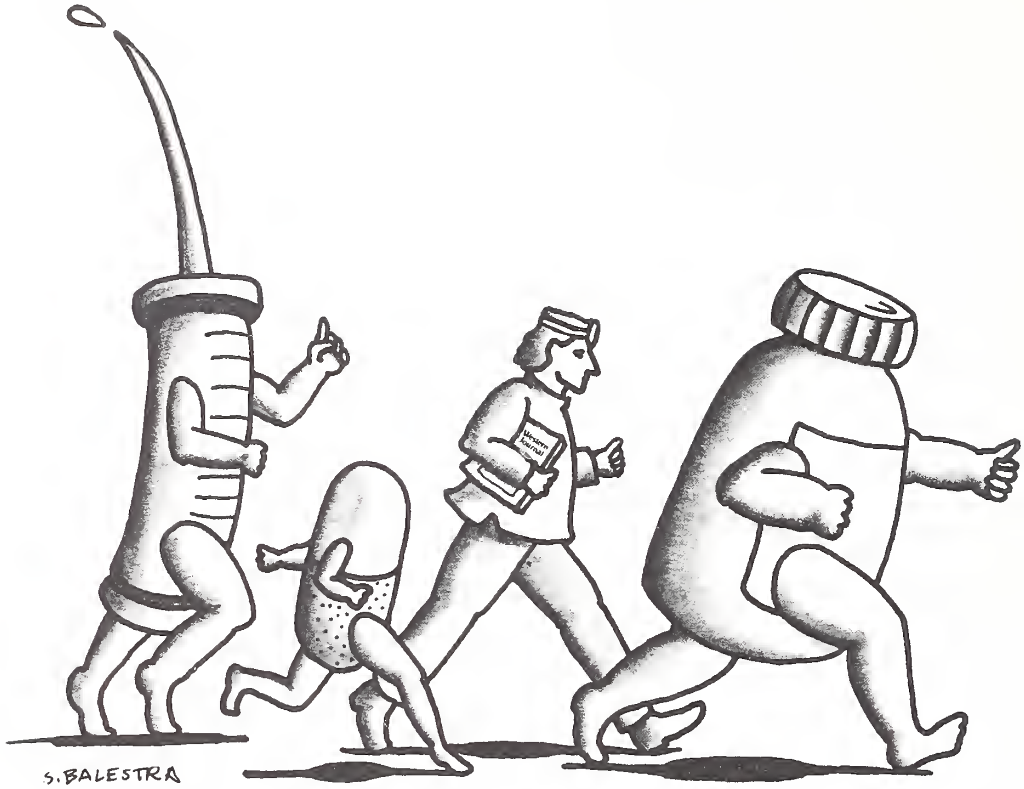

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The President's Page

Time Flies When You're Having Fun

As I write this message, I will have completed six months of my presidency. The old adage of time goes by fast when you are having fun" could not be more true. It seems like only yesterday that the House of Delegates voted to go forward with the statewide IPA-HMO and we have submitted our license application to the Insurance Commissioner. We have developed an innovative method of reimbursement. Dr. Fred Hyde, its developer, calls it a "Usual and Customary Fee with a Cap and Tax." From a legal point of view, it is important that we not have a fee schedule and from a practical point of view a fee schedule will only lead to disharmony. It has been shown time and again that if a maximum fee is established those people who are above it are unhappy and will not participate, while those below the maximum raise their fees to meet it. With our system currently being refined, the outliers will be capped at a percentage above the norm. The "tax" refers to the redistribution of 25% of the withhold that would normally be returned to those at the top of the range, to those physicians who are below the norm, in order to raise their income closer to the average. In addition, all fees will be frozen at the October 1, 1986 level for two years or until enough data is collected to insure the integrity of the program. I'm sure you will be hearing much more about this in the very near future.

The prospectus for the stock offering is in its final stages now and probably will have been distributed by the time you read this article. Until it is published we cannot discuss it, but I can tell you that the concept of "one man, one vote" and only physician-owned stock has been preserved.

Turning to a new subject, I would like to urge all members who have not contributed to COMPAC this year to please do so. The elections will be over by the time this article is published, but in order to assist those legislators who helped us last session get reelected this year, COMPAC had to borrow fifteen thousand dollars. We felt that there was additional support in the medical community but we could not wait since time was of the essence and therefore the need for the loan. As you are aware from my last message and from your newspapers, there will be a big push this year for mandatory medical assignment tied to licensure. We will need all the help we can get to defeat this onerous type of legislation and your contribution to COMPAC will help immeasurably.

On the same subject, once again it is most important for all of you to return your acceptances of the Medicare Courtesy Card program to your county offices or the State Society if we are coordinating the program for your county. I would like to stress that even if you accept assignment 100% of the time please fill out the form anyway. For our opponents, numbers will be important so no matter how many or how few Medicare patients you see, JOIN THE PROGRAM.

Joseph C. Czarsty, M.D.
President

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Reflections on Medicine

House Calls

By the turn of the century doctors, especially in towns and cities, were beginning to discourage house calls. They were urging their patients to come to their offices, and were recommending hospitalization for serious illness. The decline of the house call resulted from many social, economic, and technologic changes in the late 19th and early 20th century. Although the change was gradual and not the same everywhere, it symbolized for many patients and not a few doctors the loss of something precious in their relationship, something associated with an earlier, simpler, and better time.

Forty years ago, after the war when the science of medicine had begun to make a difference, we argued that the home was no place for scientific medicine; without a laboratory and the availability of x-rays and EKGs how could we diagnose and treat properly even such simple complaints as sore throats, coughs, chest pains, and belly cramps? We were partly right about that; usually the patient's history and clinical signs would have been good enough, but sometimes we doubted our judgment and ended by bundling the patient into a car to take her to the hospital. Soon we were telling patients to meet us in the emergency room, forgetting how miserable this would be for a child with a fever of 103 degrees or a frightened, confused old man who had been vomiting since supper. Patients continued to ask new doctors if they made house calls, but they knew that the qualified *yes* generally meant *no*. Between 1957 and 1967 the number of house calls fell more than 40%, and it has continued to fall.

That may, however, be changing again, partly because with the increasing number of physicians there is more competition for patients, and partly because of the changing nature of illness, disability, and the aging of our population. Acute infectious disease in the young has been replaced by chronic disease and disability in the old; in many instances both are best managed at home.

In an ideal system of medical care there would be ambulatory clinics and physicians' offices, an acute care hospital, a nursing home with all levels of long and short term care including rehabilitation and day care, and complete home care services, all organized around the health needs of the community and not for the profit of the investors. In a few places in our state such systems are beginning to take shape; they will be made to order for the clinical education of medical students and nursing students.

Home care services may range from an occasional visit by a homemaker-home health aide to full scale around-the-clock nursing. Home care may be the best way to manage convalescence after a hip fracture, or to provide for the final months and weeks of a patient with terminal cancer.

Nurses are taking the lead in looking after the needs of patients at home, and they can do that well when they have the resources of a nursing home and hospital to fall back upon, and when they can work in partnership with physicians. That may require physicians to delegate more to nurses; it may require changes in statutes and regulations to permit nurses to pronounce a patient dead when the end comes; and it will require physicians to make house calls, perhaps to make regular rounds on their home-bound patients.

Our critics tell us that we have designed the organization of medical services for our own convenience. That would be expected; medical care has been, for most of its history, a scarce resource, and the demands upon it have been great; for it to work well it had to be efficient. Now we are told that the system has excess capacity, which means more competition and paying more attention to patients' needs. Whatever the reasons, economic, social, technologic, or demographic, home care services are growing rapidly, and physicians are needed to make them work well. That will mean that physicians will have to help in the planning, and that medical schools, worried about the shortcomings of tertiary care teaching hospitals for student education, will turn to home health services and nursing homes for clinical education. In a troubling time for medicine this is a good development.

ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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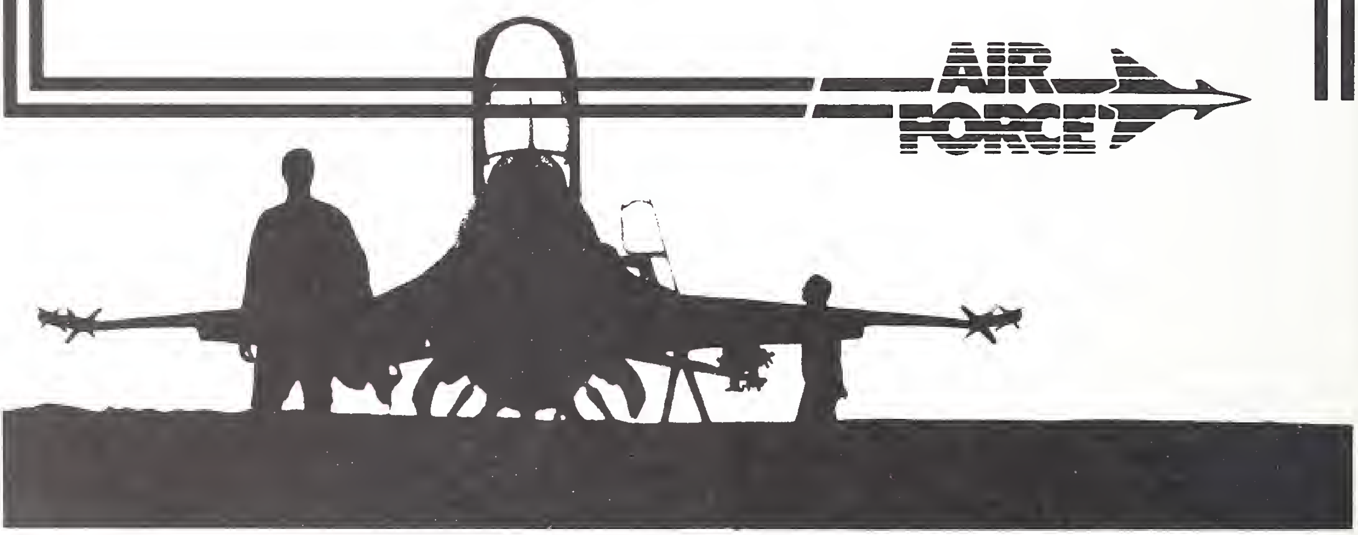


Clarifying the Therapist's Duty to Warn Potential Victims

JOSEPH M. HEALEY, J.D.

Charles and Margaret Peck brought suit against the Counseling Service of Addison County, Vermont, to recover for damages to their property. As described in my last column, their son, while receiving outpatient therapy at the Service, disclosed an intent to burn his father's barn. One day later, despite a promise to the contrary, the son set fire to the barn which was completely destroyed. The parents alleged that the Counseling Service was negligent for failing to protect them from the threat of harm posed by their son. The trial court dismissed the case with prejudice, determining that under existing Vermont law, there was no basis to establish that the Counseling Service owed the parents such a duty. The Vermont Supreme Court reversed,[1] holding that with respect to the central issue: (1) the mental health agency had a duty to warn the parents that an outpatient had threatened to burn down their barn, and (2) that the failure of the mental health agency to disclose to the parents the threat constituted a breach of duty owed to them. The Court reversed the lower court decision and remanded the case for entry of judgment consistent with its holding.

In its decision, the Vermont Supreme Court focussed on three major questions: (1) the extend to which the relationship between a community mental health agency and a voluntary outpatient gives rise to a duty to protect third parties; (2) the adequacy of the good faith judgment by the therapist in this case that the son would not burn the barn; and (3) the extent to which the duty of confidentiality to the patient outweighs other duties.

With respect to the first question, the Court rejected the contention that absence of control over the patient by the therapist in an outpatient setting should limit the therapist's duty to protect third parties. Without discussion or explanation, the Court simply concluded that whether or not there is actual control over an outpatient in a mental health clinic which is similar to that exercised over institutionalized patients, the relationship between a clinical therapist and a patient is sufficient to establish a duty to exercise reasonable care to protect potential victims of the patient's conduct. The Court pointed out that such duties exist with regard to venereal diseases and other contagious diseases and that there was no reason not to apply the underlying principle to situations involving mental illness. The Court further refused to accept the difficulty of predicting dangerousness to self or others as a reason to bar recovery in all such situations. The standard of care used to evaluate the therapist's behavior takes into account such difficulties and acknowledges the limitations involved.

With respect to the second question, the Supreme Court concluded that there was sufficient evidence to support the conclusion of the trial court that the therapist did not act as a reasonable prudent counselor because her good faith belief that John Peck would not burn the barn was based on inadequate information and consultation. Of special significance was the testimony of the parents' psychiatric expert that given the son's past history of impulsive, assaultive behavior, his medical treatment for the control of epilepsy, the possibility of a brain disorder associated with epilepsy that increasingly diminished his capacity for exercising good judgment, and a history of past alcohol abuse (all of which were known to the therapist) the failure of the therapist to reveal the son's threat was inconsistent with the appropriate standards of the mental health profession. To make matters worse, the therapist did not possess the son's most recent medical history. The Counseling Service's own expert testified that a therapist cannot make a reasonable determination of a patient's propensity for carrying out a threatened act of violence without such information. The Supreme Court viewed all this evidence as supporting the trial court's conclusion that there was a breach of duty to take reasonable steps to protect the proposed victims.

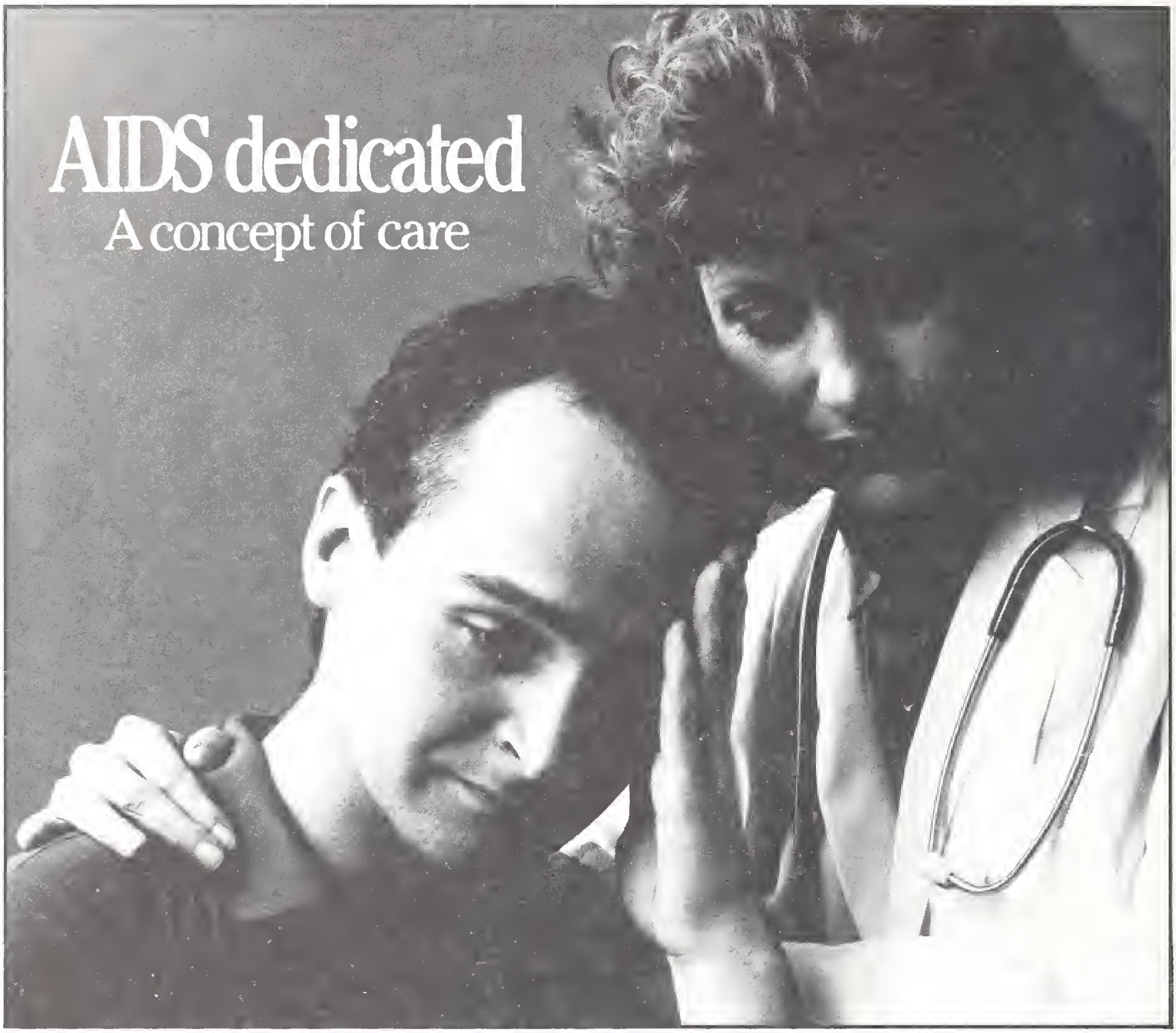
With respect to the final question, the Supreme Court, while acknowledging the importance of confidentiality in the therapist-patient relationship, emphasized that under appropriate circumstances, in the interest of public policy, the duty of confidentiality may be outweighed by other considerations. In the case at hand, the Supreme Court concluded that a mental health professional who knows or, based upon the standards of the mental health profession, should know that a patient poses a serious risk of danger to an identifiable victim, has a duty to exercise reasonable care to protect such person from that danger.

Discussion of the implications of this case will conclude in next month's column.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

REFERENCE

1. Peck v The Counseling Service of Addison County. 1985. 499 A.2d. 422.



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A concept of care

Photography by Ken Nahoum

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Connecticut Medicine

The Journal of the Connecticut State Medical Society
160 St. Ronan Street, New Haven, CT 06511

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Editorials

Watching Our Worst Prophecies Come True

It is not nice to be an "I told you so" but our concern many years ago about the inadequacies of the Medicare program seem to have developed into the predictable guagmire that government intervention usually gets into in such cases. These wonderful older citizens that we have done many things for in an effort to help them, have turned angrily upon us. Despite the efforts of Timothy B. Norbeck, our Executive Director, Dr. George Bonner and many others, senior citizen groups will not let us get our view point across. Let's look at a few of these misunderstood facts.

1. Many complaints leveled against us are outside of our jurisdiction or control. (Some seniors have mentioned the high cost of medications and hospitalization for which we perform no billing procedures but are blamed, etc.) Beside medical care, it could be pointed out that gas stations, food markets, and even liquor stores have no particular discount basis for senior citizens.

2. There is every reason to believe that a high percentage of physicians accept Medicare payment without "balance billing." Although only about 20% have indicated their acceptance of full government frozen fees for such services, a very large majority of the other 80% do not do any balance billing for senior citizens. It should be noted here that a high number of physicians participated in a voluntary fee freeze even before the government freeze program came along. The reason that many of us did not sign up with the government was that it was expected that the government would not keep its word on the duration of such freeze. (As we all know, the government did indeed break this promise and continued the fee freeze.)

3. Many figures have been given showing that an important number of senior citizens are financially well off. Does it seem fair to charge the hard working grandchildren of these senior citizens more so that they can enjoy this smaller fee? Statistics have shown that there is a progressively smaller group of working younger folks supporting an ever larger retirement group. This is acceptable except that, as mentioned above, a fair number of senior citizens are considerably better off financially, better able to pay their own way than are their hard working grandchildren in the 30-40 year old age group. This government-designated fee is based on a schedule now about five years old. 80% of this fee does not do much for the soaring overhead office costs which somebody should have the honesty to acknowledge. It seems to me that the most painful of all denouncements comes when we put forth a program aimed altruistically at helping others and it is thrown back in our faces as some sort of subterfuge. In order to make it easy to identify such needful senior citizens, the Hartford County Medical Association deserves great credit for developing the "courtesy card program." This has been now extended to the Fairfield and New Haven counties with good acceptance of this matter of verification for the patient to receive Medicare payment without balance billing. The senior citizens have tried to make a case for "you show me your 1040 IRS form and I will show you mine." Actually, such eligibility is determined through social agencies and could and should not be considered a matter for a doctors' office to verify. This seems to be no infringment on private rights, especially when one is using this to obtain services which the doctor is quite willing to provide to these senior citizens. It almost seems that the United Seniors for Action and other groups have overtly chosen to disregard the working realities behind this plan. It has certainly worked thus far and I think that a reasonable person should have given it a further trial before denouncing it.

4. Many senior citizens in Massachusetts felt that this would give them no medical bills whatever to pay. It is true that many doctors have seen fit to forego the 20% which the patient is supposed to pay (with the government paying the other 80% of an alleged reasonable fee). It has now come to pass that Health Care Finance Association (HCFA) has threatened legal action against doctors for not pursuing the other 20% of their fee. As in the case of the courtesy card, we are "damned if we do and damned

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Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

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if we don't." I have served on the Medicare Committee at a county level and fully feel that most of my colleagues agree that we have to be sure that our previously hard working and now retired senior citizens do not forego medical care for financial reasons. I believe that it is easy for us to understand how such elderly people feel when faced with the uneasiness and insecurity of serious illness and the accompanying financial drain that can go with it. Believe me, we are trying to respond to this insecurity.

Some practical solutions could include the following. Encourage our colleagues to do the very best that they can to accept the courtesy cards and minimize expenses whenever possible and wherever possible for our worthy senior citizens. We should continue to speak out at senior groups, and even individually with our older patients, on these matters. Although some senior citizens have apologized to our doctors and speakers for disruptive actions at such events, it has prevented the large number of senior citizens and the media from getting the true message.

Some of our outspoken senior citizens have shown their antagonism toward the medical profession in the unreasonable way of suggesting that Connecticut medical licensure be tied with acceptance of Medicare as a condition for such licensure. The qualifications for licensure for medical practice were clear in the Massachusetts case, wherein it was stated that such qualifications were those of competent training and high ethical and moral standards as conditions for licensure. The participation in government schemes should not distort this principle. As discussed in *Connecticut Medicine* and other places, it is the intention of the AMA to develop a new program to supplant the Medicare program and this deserves great attention from all of us. If Congress could look at it objectively, it would answer many of the deficiencies of the present program (for patients and doctors alike). At a time when we are in deep controversy with the malpractice problem and its related expenses; at a time when we are trying to do the best we can with the "alphabet soup" of PROs, HMOs, DRGs etc., etc., it is even sadder that the people that we have tried to befriend and help with their health problems, have seen us as adversaries instead of allies.

Stewart J. Petrie, M.D.

Defensive Medicine

For the past 35 years, a substantial part of my law practice has been in defending physicians against malpractice claims. My views on defensive medicine reflect this experience.

Intelligent discussion of the pros and cons of defensive medicine have been hampered for lack of a uniform definition of the term. Most commonly defensive medicine is used to describe diagnostic and treatment procedures which a physician performs with the intention of protecting himself if he is sued for malpractice, and not for the benefit of the patient. Although this concept of defensive medicine conflicts with the ethic that a physician should place the interests of his patient above his own, nevertheless such practice is often condoned as a necessary evil in the present climate of medical liability.

Frankly, I strongly disagree with this concept of defensive medicine. There is no dichotomy between what is best for the patient and what is best for the doctor. They are one and the same. With rare exceptions I have found that the opportunity for a successful defense is substantially enhanced to the extent that a physician-defendant can demonstrate that he has observed the rudiments of good medical practice. I have also found that some physicians who have engaged in diagnostic and treatment procedures which they considered unnecessary except for the purpose of defense if they were sued, actually found that what they had done proved to be the basis of suit against them. For example, invasive diagnostic procedures that cause death or injury, even if skillfully performed, may be difficult to defend where justification for the procedure is in issue.

It has been reported that $75.4 billion was spent on physicians' services in 1984 and that of this amount $17.5 billion was attributable to defensive medicine. Presumably this estimate refers to the cost of medical services that physicians would not have performed were it not for fear of being sued for malpractice. This does not mean that all of these services were worthless and of no benefit to patients. I believe that it is appropriate to say that the possibility of being sued for negligence does inhibit carelessness and fosters prudence in some physicians.

Our firm has tried or settled thousands of malpractice cases. Based upon our experience, the vast majority of diagnostic testing that might be classified as defensive medicine in hindsight proved to be clinically appropriate in the best interest of the patient, and incidentally in the defense claims. On the other hand, we have experienced difficulty in defending physicians in a variety of situations in which certain diagnostic tests were not performed but which were contended by plaintiffs to be negligent omissions. Despite new sophisticated technology for the diagnosis of cancer, failure to diagnose cancer is frequently the basis for medical liability litigation. Failure to diagnose fractures also account for a significant volume of claims. The most alarming statistics involve claims related to births where improper treatment is attributable to failure to diagnose pregnancy problems.

The patient is not the doctor's adversary. It is a disservice to the medical profession to encourage physicians to think in terms of defensive medicine when they care for patients. The only admonition warranted is that the physician should engage in good medical practice to the best of his ability. He should maintain good records, keep the patient informed at all times and stay abreast of current developments in his field of practice.

Max E. Wildman, J.D.

Mr. Wildman is a partner in the law firm of Wildman, Harrold, Allen & Dixon in Chicago.

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Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

A SELF HELP MANEUVER IN ANGINA

To the Editor: The *bête noire* of heart attacks is silent ischemia. Heart disease is treated by nitrates, beta blockers, and calcium blockers. Cardiac collapse is treated by CPR, for blood flow started by rhythmic chest compression is more immediate than effects achieved with any drugs. The most effective post-infarction regimes include adequate programs of exercise and do not depend entirely on responses to pharmaceuticals.

The "silence" of silent ischemia is not total; case histories of infarction show that "premonitory" symptoms of pain were ignored for as long as a month. The problem of ischemia with angina involves lowered blood flow and inadequate oxygen supply. A mechanical maneuver can be used that promptly relieves an attack. The maneuver of immediate rhythmic contraction of the abdominal muscles and rapid, pursed-lips expiration has provided symptomatic relief. Patients can do this while reaching for nitroglycerin and waiting for it to take effect.

Part of the heart's work is to suck blood from the vena cavae and the pulmonary veins. The abdominal contractions and the expirations are simultaneous and can be forceful. Abdomen muscles assist the venous return to the heart and reduce demand on the myocardium. The voluntary chest movement also provides dynamic help for blood flow from the lungs to the left atrium. Increased intrapulmonary pressure with (pursed lip) expiration enhances oxygen passage through the alveolar-capillary membrane. Voluntary hyperventilation can change the O_2 tension from 95 to 97 as shown by oximeter monitoring, no pharmaceutical effect alone equals this improvement.

This "Self Help Maneuver In Angina" (SHMIA) harmonizes the complex of "supply and demand" of glucose and oxygen for heart muscle. The improved venous return and the enhanced alveolar-capillary diffusion of oxygen parallels the timely twists of an automobile steering wheel which avoids a collision. Infarction is the end result of a chain of events, and SHMIA achieves an early turn-around at a stage when only a small force is needed to change the direction from deterioration to compensation, and restore homeostasis.

The rhythmic contractions by the patient can be inconspicuous and the exhalations noiseless to avoid attracting attention. This simple maneuver works, for it is started within a second after chest pain is felt. The heart never rests, blood flow must be continuous and many variables add up critically at odd times in the supply and demand process. The aging heart with weaker muscles and narrowing blood vessels still accommodates even when the patient forgets to slow down. SHMIA smooths out transient overloads and puts the blood where it is needed when a warning occurs.

SHMIA is worthy of clinical study. It is worth finding out whether SHMIA for "premonitory" attacks of MI may entirely avoid the subsequent infarction.

Sidney Vernon, M.D.

Willimantic, CT

The above letter was referred to Dr. Hager, who offers the following reply:

To the Editor: Dr. Vernon's description of the "Self Help Maneuver" in angina is quite interesting. As you may know, there has been a tremendous amount of work on the so called cough resuscitation. It has been well documented that coughing can maintain consciousness during ventricular fibrillation for 30 to 45 seconds.

When somebody develops ventricular fibrillation in the catheterization laboratory it is possible to keep the patient conscious by having him cough while the defibrillator paddles are being charged. We also use the cough after coronary injections in the cath lab to counter the depressant effect of contrast material during coronary injections.

A number of investigators, such as Dr. Myron Weisfeldt at Johns Hopkins University have done research on the physiology of the cough resuscitation. Eventually, there will probably be a major revamping of the way CPR is taught as a result of this research. (Because of the success of the American Heart Association in teaching CPR this will entail a monumental task!).

Thus, Dr. Vernon's suggestion of having a patient essentially strain or Valsalva and breathe against a closed glottis is a type of coughing maneuver. I have not seen this evaluated in the setting of the treatment of anginal pain itself. Rather, it is used to augment flow through the heart and into the coronary circulation. A cough generates probably more pressure in the chest than any chest compression can generate. In addition, a cough is often followed by a vigorous inspiration which, in turn, leads to an increase in venous return.

Dr. Vernon's suggestion is probably worthy of some study. If he has data on the effectiveness of the cough in treating angina, itself, I would be most interested.

W. David Hager, M.D.

Director, Clinical Cardiology,
University of Connecticut School of Medicine,
Farmington, CT

MANAGING CHANGE

To the Editor: In teaching civilization and the arts to the populace Prometheus transgressed the will of Jupiter and was banished from the land and chained to a rock at Mount Caucasus to suffer elemental torture. Centuries later he was "unbound" in martyrdom by the creative literary genius of Percy Bysshe Shelley in the following words:

> I would not quit this bleak ravine,
>   these unrepentant pains.
> Pity the self-despising slaves of Jove.
> Not me within whose mind sits peace serene.

Perhaps the magnitude of influence is not comparable in deed but certainly in spirit by some of our medical editors and long experienced "reflection writers." Our profession can be proud of the Bob Masseys and Bud Relmans in this ever difficult and changing medical environment. Let us be certain that the health of our society is reflected in not just answers but answers that respond to the proper questions. Cost-benefit ratios, experimentation versus acceptable clinical practice, patient interest-physician interest conflict, trust and confidentiality, ethical decision making, and what does it mean to be human are but some of the very pressing issues and questions our medical writers are addressing.

I believe that success in life is the capacity to effectively manage change. A good health care system (as good health itself) is not a gift but an achievement. I was delighted to read in the October issue of your commitment to record the change events and "help us to understand their significance" despite the first Hippocratic aphorism.

Alan F. Krupp, M.D.

Manchester, CT

COMMITTEE SERVICE QUESTIONNAIRE
Connecticut State Medical Society

Early in 1987 the Councilors from the eight constituent county medical associations assume the responsibility of selecting members of the Society to participate in the various activities of the Society listed below. In making these selections it is of importance to choose physicians who are not only willing and able to serve but also who are known to have an interest in the work of the group to which they may be assigned. In order to enable this office to furnish the Councilors with a compilation of those who desire to be considered for committee service, all members are asked to indicate by number in order of preference (not more than three) opposite your choice in the questionnaire below and return same to the:

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Your cooperation will be appreciated.

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☐ Committee on Hospitals
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☐ Liaison Committee with Connecticut Pharmaceutical Association
☐ Liaison Committee with State Department of Income Maintenance
☐ Representatives to Connecticut Advisory School Health Council
☐ Delegates to Connecticut Public Health Association, Inc.
☐ Delegates to Connecticut Nutrition Council
☐ Delegates to Council of New England State Medical Societies

Please Return by January 20, 1987

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Shelley A. Marcus
Director of
Government Relations

Council Meeting
Thursday, October 23, 1986

Attendance

Present in addition to the Chairman, Dr. Guy W. Van Syckle and Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahamed, Beck, Bobruff, Bonner, Czarsty, Dardick, Finn, Jr., Freedman, Friedberg, James, Kamens, McDonnell, O'Brien, Orphanos, Ragusa, Reyelt, Jr., Robbins, Rose, Sadowski, Sullivan, Jr., Sweet, Villa, Waldron, Welch, Zanker and Zlotsky.

Also present: Dr. Massey, Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Sullivan, Mr. Staples, Mr. Tomat and Mr. Coffey.

Absent were: Drs. Ahrens, Canzonetti, Fox, Petrie, Schwartz and Wetstone.

Report of the President

Dr. Czarsty reported that the Task Force To Study Tort Reform had discussed the issue of placing a cap on pain and suffering damage awards and will be considering whether or not to make a recommendation supporting such a cap.

The Ad Hoc Committee To Study Medicare Assignment cancelled its October meeting, possibly for political reasons.

Dr. Czarsty mentioned that COMPAC remains in need of financial contributions, particularly if it is to adequately support friends of organized medicine during the 1986 legislative campaign. Phonebanks were used very successfully in Middlesex County, and are planned for the Waterbury area in the coming weeks.

The content and format of the Leadership Conference was well received. In view of its educational value, suggestions were made as to how to broaden its appeal to more CSMS members.

Dr. Czarsty read a letter to Ms. Barbara Bresler, Chairperson of The Connecticut Board of Mental Health, expressing the willingness of the Connecticut State Medical Society to assist in the search for a new Commissioner. The Council VOTED to approve the letter to Ms. Bresler.

Report of The Executive Director

Mr. Tim Norbeck reported that the American Trial Lawyers Association had targeted Connecticut and Washington for repeal efforts due to the extensive reform packages enacted in both states. Continued political action by CSMS is necessary to successfully fight these efforts.

He reported that the Medical Courtesy Card program was going well statewide, and that applications and information forms have been sent to senior centers and municpal agents, and responses are still coming in from physicians. Press releases have been sent to all media outlets, and follow-up interviews have been conducted with key radio and newspaper reporters. The formal press conferences will be held in mid-November, once sufficient physician participation is achieved.

Mr. Norbeck provided a brief summary of the Massachusetts situation following the passage of mandatory assignment legislation. A federal judge upheld the law on the grounds that it did not violate the Supremacy Clause, and on the grounds that states may enforce socioeconomic policies through the licensure process.

Dr. Zanker suggested that information concerning the Massachusetts legislation be included in future COMPAC mailings.

CSMS IPA-HMO Update

Dr. Czarsty mentioned that the IPA-HMO was continuing its development and that a new name, M.D. Health Plan has been adopted by the Steering Committee.

Attorney Barry Scheur, Project Manager, explained that a prospectus for the HMO stock offering was being prepared and would be available shortly. He also mentioned that he and Attorney Eve Horowitz had received very favorable reactions from Insurance Department representatives concerning the IPA-HMO license application.

Results of a fee survey from IPA enrollees were revealed, along with a Steering Committee recommendation that a fee-for-service methodology should be utilized by M.D. Health Plan. The survey results indicated that wider discrepancies existed within counties for a given code, than between counties. This encouraged the Steering Committee to recommend that physicians be paid based on their usual and customary fees, as they existed on October 1, 1986. In addition a mechanism is being developed to review outlier fees in each CPT code. Finally the committee is studying a mechanism to determine if a minor portion of the withhold pool could be redistributed to physicians whose fees are at the lowest end of the CPT codes.

Extensive discussion ensued regarding the fee-for-service proposal. Concerns included the financial soundness of such a plan, the implicit advantages for physicians charging higher fees and disadvantages for those charging lower fees, and failure to address perceived regional inequities.

It was explained that fees would be fixed at the October 1, 1986 levels for two years to assess the viability of the fee-for-service methodology. In addition, a clause would exist permitting immediate abandonment of this method if its failure became evident.

The Steering Committee was praised for the long hours and dedication of its members to this undertaking. It was VOTED that the written and oral reports of the Steering Committee be received as information and to complement them on their work.

The Council discussed a potential "bridge loan" that the Steering Committee might request in order to continue operations until stock sales begin. Possible delays in the capitalization process may require such a loan proposal. Following discussion, it was VOTED that the Council convey the necessary information about co-signing a "bridge loan" for the M.D. Health Plan to the House of Delegates for their action. *The Council recommends the House's approval.* There were no dissenting votes on this proposal.

The Council also discussed plans for seeking repayment of feasibility funding provided by CSMS to the IPA-HMO project. On recommendation of the Fiscal Subcommittee, it was VOTED that the Council request the directors of the IPA-HMO to sign a note for funds expended by the Connecticut State Medical Society in undertaking these entities. The note to be interest free for two years (beginning 11/1/86), following which interest will be charged at prime rate. It was further VOTED that the discussion of further funding of the M.D. Health Plan should be placed on the House of Delegates agenda prior to the presentation of the 1987 budget.

Drug Utilization Review Committee (DURC)

In reply to a request received from the Connecticut Department on Aging seeking a nomination of a physician to serve on the subject committee, it was VOTED to recommend the name of Vincent O'Neil, M.D., of Newington.

Prescription Abuse Date (PADS)

On recommendation of the Fairfield County Medical Association Board of Trustees, it was VOTED to investigate the possibility of having the AMA establish the PADS program in Connecticut.

Fiscal Subcommittee

Review of 1987 Budget

Dr. McDonnell, Treasurer, presented the budget for 1987, as prepared by the Fiscal Subcommittee. Following discussion the following actions were taken:

VOTED to raise the honorarium for the President of Society from $2500 to $3000;

VOTED to table a motion to authorize the reimbursement of expenses of the President and Chairman of the Council;

VOTED that the CSMS membership dues for 1987 remain at $275.00;

VOTED that the 1987 Budget, as amended, be approved by the Council, and transmitted to the House of Delegates on November 19, 1987, with the Council's recommendation that the dues structure and budget be approved by the House of Delegates.

Report on CMMI and CMIC Activities

In accordance with Council action of 3/21/85 that prior to each House of Delegates meeting, there should be a discussion and report on CMMI and CMIC activities, Dr. James Orphanos, President of CMMI, reported as follows:

1. That the 1986-87 policy enrollment period showed a moderate growth. In 1986 CMIC had 1750 member insureds; the enrollment as of October 15, 1986 is 2125. Ninety-nine per cent of the existing insureds have been renewed and almost 400 new members added to CMIC.
2. CMIC's current invested assets are now approximately $33,871,000. This number does not include assets due the Company for premium and surplus contributions in the course of collection.
3. Projections indicate that written premium and finance charges for the 1986-87 policy year will be approximately $18.0 million. This would be an increase of 25% over the 1985-86 policy year.
4. The new membership growth during this enrollment period solidifies CMIC as the largest professional liability insurer in the state in terms of the number of physicians insured.

It was VOTED to receive this report as information.

Report of Ad Hoc Committee on Membership

Dr. Isadore Friedberg, Chairman, reported on several items that were referred to the Committee by the Council.

1. *Membership Benefits*
   The committee discussed the value of offering to any interested member services or products which many other state and/or county medical societies commonly make available to their members. Before proceeding any further, along these lines, the committee requested the Council to permit the Committee to fully investigate these areas. It was VOTED that Council authorization be given to continue to study the idea of membership benefits.
2. Unified Membership, Section for Retired CSMS Members and Women in Medicine were also discussed and the committee will keep the Council apprised of new developments in these areas.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on October 23, 1986. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the society.*

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Please send them to:
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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Challenging full-time position available for a talented physician with experience in Emergency Medicine. Please send CV to Thomas W. Turbiak, M.D., FACEP, Chief, Emergency Medical Services, Bristol Hospital, Brewster Rd., Bristol, CT 06010.

Full-time position for E.R. physician at a greater Hartford area community hospital. Prefer an E.R. residency trained M.D. Internists/Family Practice M.D.s with E.R. experience will be considered. Competitive salary with a full benefit package. Send CV to Bradley Memorial Hospital, Personnel Dept., 81 Meriden Ave., Southington, CT 06489.

Full-time position for American trained physician in community hospital in NW Connecticut. Send CV to Lawrence Ward, M.D., Winsted Memorial Hospital, Winsted, CT 06098.

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Oct. '86. Age 58. Presently in practice. FLEX. MD, Univ. of Bologna, Italy; Int. St. Boniface Hospital, Winnipeg, Manitoba, Canada; Res., Health Sciences Center, Manitoba, Canada. Prefers urgent care in a large-sized community. Write, Vito P. Girgenti, M.D., 9 Monk Rd., Warwick, RI 20889.

INTERNAL MEDICINE

July '87. Age 30. Presently in practice. Nat'l bds. AB cert. MD, Boston University School of Medicine; Int. and Res., St. Elizabeth's Hospital of Boston. Prefers group type practice. Write, Keith J. Lerner, M.D., 1680 Beaver Ridge Dr., Kettering, OH 45429.

Oct. '86. Age 28. Licensed in Connecticut. Presently in practice. AB elig. MD, University of Connecticut, Storrs, CT; Int. and Res., St. Mary's Hospital, Waterbury, CT. MPH, Yale University, New Haven, CT. Prefers group, institutional, industrial or prepaid HMO. Write, Malinda Midzenski, M.D., 25 Van Rose Dr., Hamden, CT 06517.

Jan. '87. Age 37. Nat'l bds. AB elig. MD, George Washington University School of Medicine, Washington, DC; Int. and Res., University of Alabama Hospitals. Prefers group or associate type practice in a medium to large-sized community. Write, Les Gavora, M.D., 7521 Murray Hill Rd., #638, Columbia, MO 21046.

GASTROENTEROLOGY. July '87. Age 30. Licensed in Connecticut. Nat'l bds. AB cert. MD, SUNY-Downstate Medical Center, Brooklyn, NY; Int. and Res., Hartford Hospital, Hartford, CT; Fellowship, Nassau County Medical Center, East Meadow, NY. Trained in all endoscopic procedures. Prefers group or associate type practice. Write, Jeffrey S. Gelwan, M.D., 200 Carman Ave., Apt. 13D, East Meadow, NY 11554.

ORTHOPEDIC SURGERY

July '87. Age 30. Nat'l bds. AB elig. MD, SUNY at Buffalo School of Medicine; Int., Millard Fillmore Hospital, Buffalo, NY; Res., Washington University School of Medicine, Seattle, WA. Prefers group, associate or institutional type practice in a large-sized community. Write, Robert P. Dudek, M.D., 4980 Potomac St., St. Louis, MO 63139.

Immediate available. Age 32. Licensed in Connecticut. Nat'l bds. AB elig. MD, S.U.N.Y. Upstate, NY; Int., Westchester County Medical Center, NY; Res., New York Medical College, NY. Prefers solo, group or associate type practice. Write, Neil S. Perlman, M.D., 42 Winchester Ave., Yonkers, NY 10710.

PEDIATRICS

PEDIATRIC GASTRENTEROLOGY. July '87. Age 33. FLEX. AB elig. MD, Baghdad Medical College, Istanbul, Turkey; Int. and Res., Milwaukee Children's Hospital (Medical College of Wisconsin) (Pediatrics); Fellowship, Oklahoma Children's Memorial Hospital, Oklahoma City, OK. (Gastroenterology). Prefers solo, group, associate or institutional type practice in a large-sized community. Write, A-Salam N. Al-Hafidh, M.D., 2609 Featherstone Rd. #239, Oklahoma City, OK 73120.

PSYCHIATRY

July '87. Age 29. Nat'l bds. AB elig. MD, University of North Carolina, Chapel Hill, NC; Int., University of Pittsburgh Health Center, Pittsburgh, PA; Res., Western Psychiatric Inst. and Clinic, Pittsburgh, PA. Prefers solo, group and institutional type practice. Write, Arthur Dworetz, M.D., 2355 Tilbury Ave., Pittsburgh, PA 15217.

UROLOGY

Immediately available. No age given. MD and Int., Ains Sham University, Cairo, Egypt; Res., Albany Medical Center, Albany, NY. Prefers solo, group or associate type practice in a small community. Write, Edmond B. Grace, M.D., 28 Oakbrook Manor, Ravena, NY 12143.

July '87. Age 31. Nat'l bds. AB elig. MD, Downstate Medical School, NY; Int. and Res., Downstate—Kings County Medical Center, NY. Prefers group or associate type practice. Write, Steven A. Bernstein, M.D., 132-46 88th St., Ozone Park, NY 11417.

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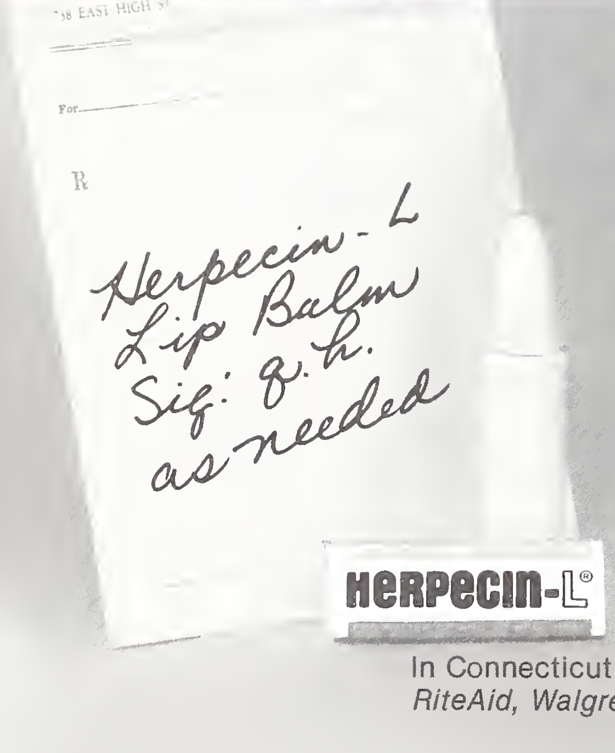

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